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AN INDEPENDENT ORGAN OF THE PHARMACEUTICAL INDUSTRY, TRADE AND PROFESSION

Vol. XXXII No. 380 SPECIAL INDEPENDENCE ISSUE August 1989

"Some patients find it easier to swallow capsules than tablets, therefore preferring to take this form when possible. This preference has prompted pharmaceutical manufacturers to market the product in capsule form even though the product has already been produced in tablet form."

— Remington's Pharmaceutical Sciences 16th edition

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— Edward J. Rowe in MARTIN'S 'Dispensing of medication' 7th edition

"Capsules generally provide ready availability of the contained drug, since **minimal excipient and little pressure** are required to compact the material as in tableting."

— Hostetler & Bellard in Lachman, et al, 'Theory and practice of Industrial Pharmacy' 2nd edition

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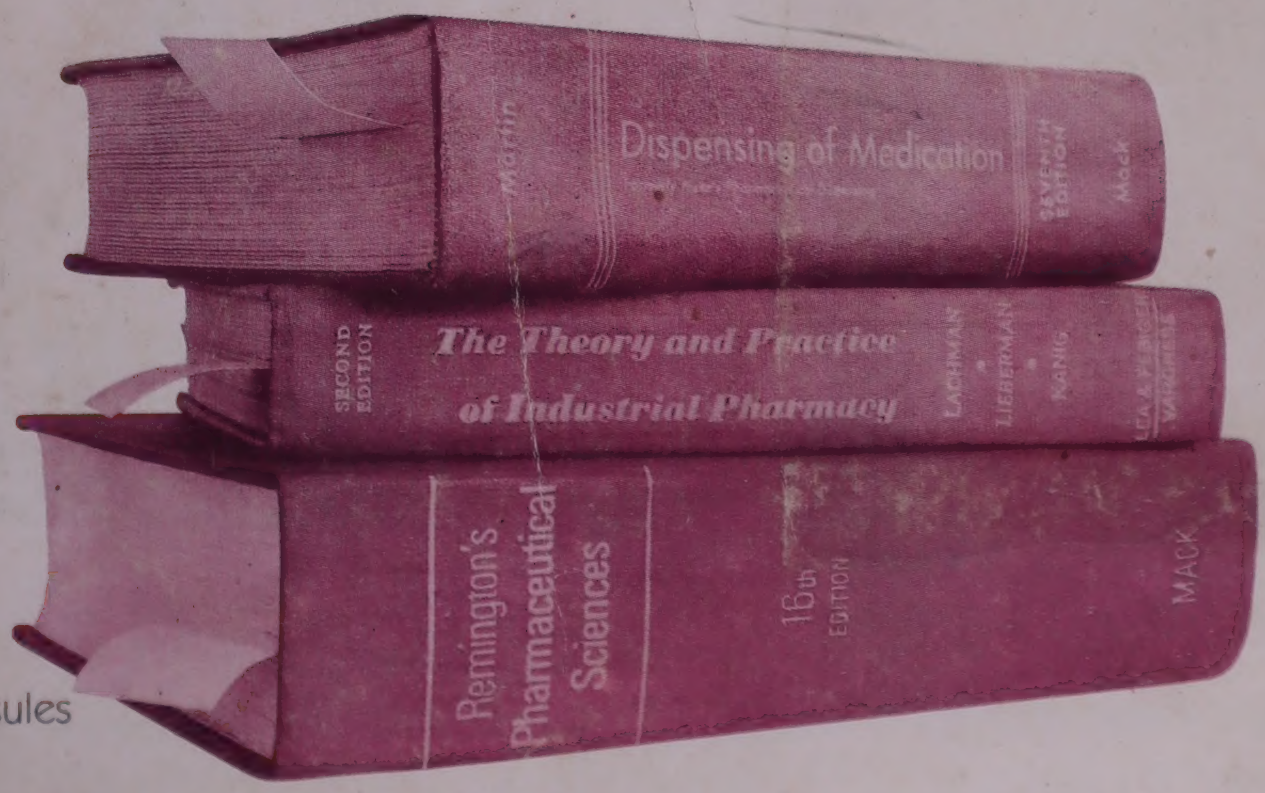

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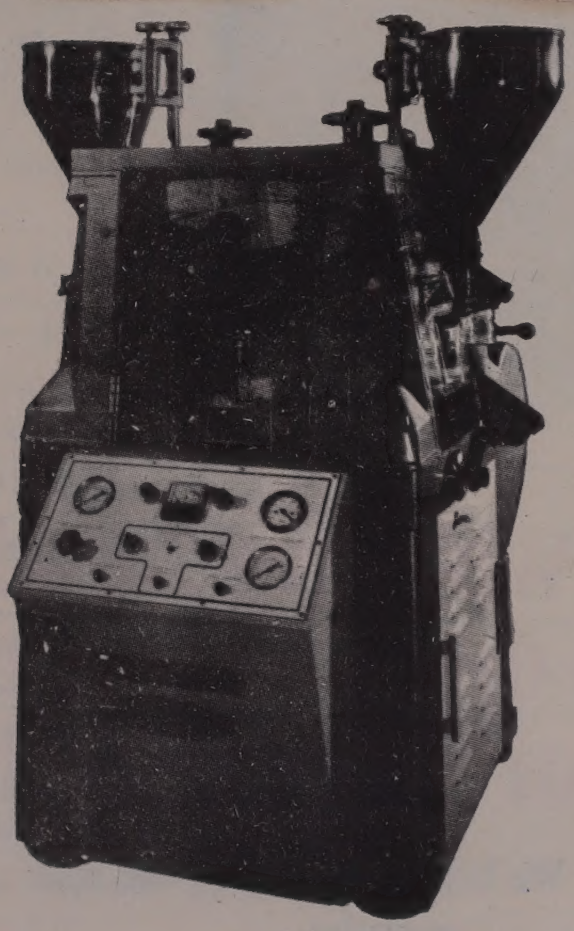

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CONTENTS

Letters to the Editor	4
Expand Drugs Control Organisation—Editorial	11
Topical Comments—Dhanwantri	13
Current Status & Problems of Pharmaceutical Industry —Dr. S. Agarwal	17
Aspirin Reveals Modern Face—Steve Chaplin	25
Good Manufacturing Practices in Preparation of Ophthalmic Drugs —S.K. Gupta	31
Rational use of Drugs : What does it Mean ? —B.P. Jaju	39
Stability Indicating Test Procedure—In Perspective—V. Kumar & N. Sunder	47
Computers in Pharmacy Management—Mathew Vergese	55
Prescribing for Medical & other Headaches—Peter Marsh	63
Development of Indigenous Technology in Drugs —Special Correspondent	69
Screening of Medicinal Plants with Antifertility & Spermicidal Activities—Dr. N. Udupa	77
Good Manufacturing Practices—Dr. M.A. Patel	81
Antipsychotic Agents (Neuroleptics) In Medicine And Pharmacy —Dr. P.C. Dandiya & Kalpana Sharma	87
Trends In Oral Sustained Release Formulations—I.H. Popli & S.N. Sharma	99
AND OTHER REGULAR FEATURES	105-180
SCIENTIFIC SECTION	
Spectrophotometric Determination Of Sulphadoxine And Sulphalene In Pharmaceutical Dosage Forms—G. Ramana Rao, S.S.N. Murty & I.R.K. Raju	185
Colorimetric Determination of Isoxsuprine Hydrochloride In Dosage Forms—Gopal Krishan, Santosh K. Talwar, S.C. Sharma & R.G. Sharma	189
High Performance Liquid For Chromatographic Method For Frusemide And Spirolactone Combination—(Mrs.) S.A. Anapure, Dr. S. Khanna & V.S. Dighe	193

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Sweet Memory of K. Kishore Bazaz who left us on 20th August, 1981. We all remember him with everlasting Love and Affection.

LETTERS TO THE EDITOR

CLOSURE OF PHARMA R & D UNITS

The report "Pharma R&D Units Close down" by Mr R.N. Bhaskar, which appeared in November 7, 1988 issue of Financial Express has come to my notice recently. Having been personally involved in Pharmaceutical industry since 1950, I have reasonable personal knowledge of this field and would like to react to some of the issues raised in the report, particularly as there is a reflection on the capabilities and contributions of the Indian scientists working in the R&D Labs. of the units that are proposed to be closed down and on Govt. policies on R&D.

The two centres mainly referred to in the report are the Eskayef Research Centre at Bangalore and the Hindustan Ciba-Geigy Research Centre (HCG) (erstwhile Ciba Research Centre) at Bombay. The Eskayef research centre was rather small and confined primarily to soil screening for antibiotics and isolation of cultures; most of the detailed and follow up work was carried out in the parent laboratory in USA. It is recognised that excellent screening and primary isolation work was carried out in the centre at Bangalore, and at a cost much cheaper than what it would have cost Eskayef in U.S.A. And that a few antibiotics arising out of this work are in preclinical development stage.

The closing of the HCG research centre, is however, a more serious matter as it was perhaps the largest and highly respected pharmaceutical basis research centre in the private sector in the country. The reasons for taking this drastic step, as given in the report and in some of the notes circulated by the Ciba-Geigy management are most unconvincing. While the right of the management of an industry to continue or not continue a research centre is no doubt absolute, the reasons given are not only not convincing but also do not put the facts in a proper perspective. It may be pointed out that HCGR Centre (erstwhile Ciba Research Centre) always has had a special 'position in Indian drug research. It was inaugurated by no less a person than Pandit Jawahar La-Nehru, in the presence of a gathering of very distinguished scienl tists, from within the country and abroad, including some Noble Laureates. Pandit Nehru in his speech had said: "I am happy to be here today, and to congratulate those responsible for this Ciba Research Centre, for what they have thought of and what they have built up here, translating their thoughts into action... it is bound to do good work, good for India and good for the world. I welcome it therefore, and wish it all success". There was a lot of appreciation of the vision and foresight of the Ciba management.

It is indeed regrettable that a research centre set up with so much good-will and fanfare is about to shut down, and without a ripple or whimper. These R&D Centres have enjoyed, common with other approved in-house R&D Laboratories in industry, benefits of generous tax concessions given by the Government under its policy of promoting industrial research and development. In effect this means that these centres have really been created and maintained mainly at the expense of the tax-payers. Closing of these centres is thus a wastage of national invesment.

Dr. M.K. Mong Hansen, Managing Director, Hindustan Ciba-Geigy is reported in the article as having said that in the 25 years of its existence their Centre has spent over Rs 75 crores out of this investment only one drug has emerged and that too is not significantly different from similar products already in the market. This statement appears like a reflection on the competence of the Scientists of the Centre, which fact is not correct, to say the least. I wonder if this statement is based on any scientific audit?

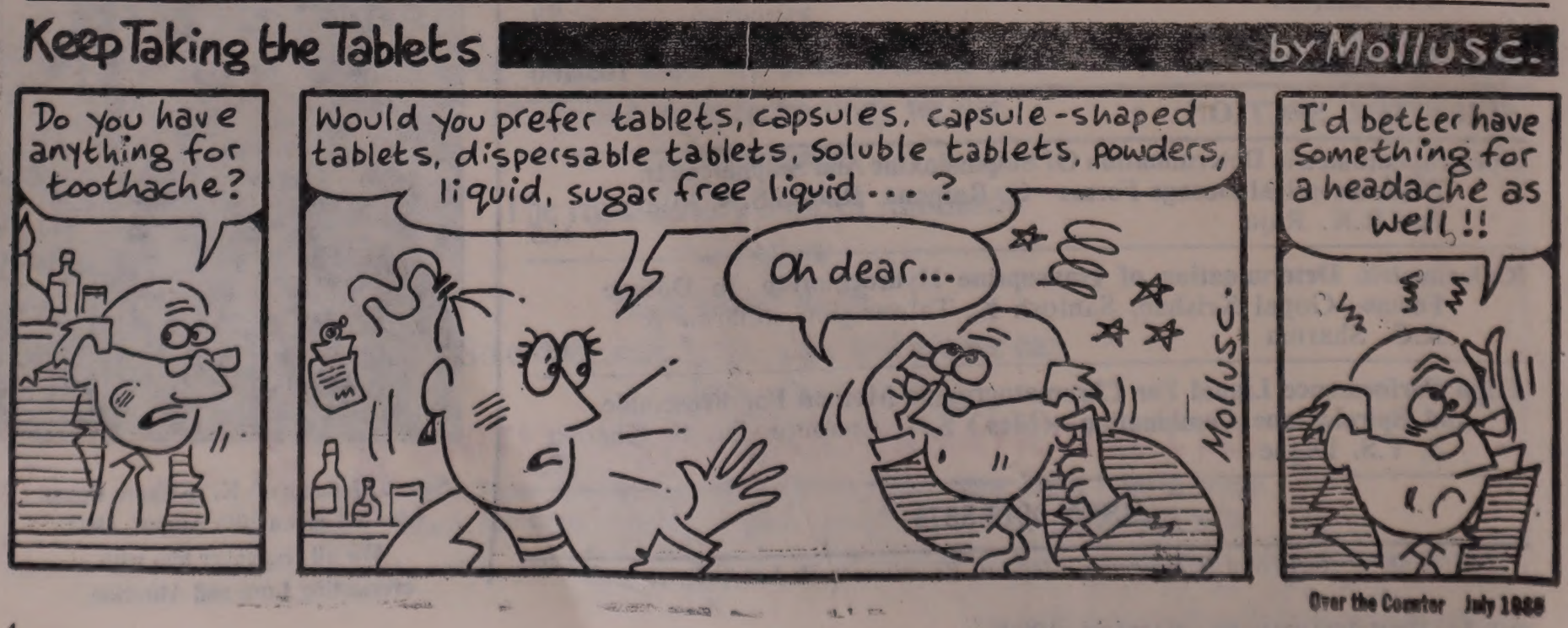
That only one drug could be introduced is due to the fact that investment in the Centre was rather low. It is quite well known that drug research is an expensive and time-consuming business and that the cost of discovery of one drug is anywhere between Rs. 50 and 100 crores. If Ciba have spent Rs 75 crores, they have invested just enough for one drug, and the output of one drug is quite commensurate with the input.

But it is also known to R&D Scientists in this area that the Centre had a number of potential drugs in the pipeline. Whle some compounds had to be dropped in the last stage because of the stringent standards of safety now required by drug control authorities, this is not the fault of the scientists. It is, moreover, known that a few more drugs discovered by the Centre are under clinical trials, some by WHO. Scientists of this Centre are most competent have been contributed much to drug research.

Even the research by the Ciba principlas at Basle has not resulted in major discoveries in the last 25 years, which is no reflection on the competence of the research staff. This is part of the challenge of drug research. I do not have the figures of the annual investment by Ciba, Basle, in R&D, but I do know that a foreign company of equivalent size invests some Rs. 300 crores a year and even then not many drugs are discovered for many years. With Rs 75 crores spent on rsesearch spread over 25 years, by Hindustan Ciba-Geigy how much output could it expect?

The Hindustan Ciba-Geigy Research Centre has been an acknowledged Centre of excellence, and its scientists have received recognition for their scientific contributions; many of them have won national awards. The scientific community in India had always complimented the erstwhile management of Ciba for their foresight in recruiting such excellenent staff and creating such a good research Centre.

Mr. Mong Hansen is also reported to have said that they have decided to change their emphasis in tropical medicine research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from classical chemotherapy to prophylaxis with vaccines, and hence the decision to close down their Research Centre. This argument is not convincing. Our Government is giving emphasis to promoting biotechnology. If Hindustan Ciba-Geigy were to reorient their R&D programmes to biotechnology, this would be in conformity with nation R&D policies and current world trends in pharmaceutical research, and would avoid closure of the Centre.

In the same article it is also mentioned implied that the management has not been able to recruit suitable biologists/immunologists to match this shift in emphasis, which is also not very convincing. If there is one field in which in recent years Indian scientists working in Europe and North Amercia have done extremely well, it is molecular biology/biotechnology and Hindustan Ciba-Geigy could offer suitable terms to such expatriates to return to India.

Further, it is during this period that ASTRA AB, Sweden has set up an excellent Research Centre in Bangalore devoted only to molecular biology and immunology, with emphasis on development of vaccines and diagnostc tools based on immunology. In the Government Sector too, two excellent research laboratories have been established, the Institute of Microbial Technology at Chandigarh and the Centre for Cellular and Molecular Biology at Hyderabad. While, the former has application-oriented biotechnological programmes the latter specializes in research on basic biotechnology. I am told that a majority of the R&D scientists working in these laboratories have come to work there after spending many years in research centres in USA and Europe. Obviously, they must have found the invitation to join these laboratories attractive.

The question now arises why have Hindustan Ciba-Geigy and others, as reported to Mr R.N. Bhaskar, decided to stop their research. The position of the Indian Pharmaceutical industry is rather paradoxical. It is amongst the most highly R&D based industries, and R&D does need large investment both capital and recurring. But this Industry deals with products which meet a vital social need, and the cost of drugs cannot be allowed to rise too high because the large majority of the people will not be able to afford the drugs, and the purpose of the Industry will be defeated. The Government has, therefore, kept various controls and checks on the pharmaceutical industry in India, due to which its profit margin is rather very low (when compared to the pharmaceutical industries of Euorpe and USA), and the Companies have, therefore, not too little to spare out of their profits for R&D. But now the Government, taking cognizance of profit ceiling, has reintroduced liberal incentives to firms setting up in-house R&D Centres. This definitely offsets the low profit margin and leaves no cause for the HCG management to close down the R&D Centre.

May I take the opportunity to urge through the columns of your esteemed daily to the management of Hindustan Ciba-Geigy to reconsider their decision of closing down the Research Centre? This would give a chance to their R&D scientists to again show their creative best and would help them in coming out of a state of despair and helplessness and would restore their self-confidence.

New Delhi. Dr. Nitya Anand.

* * * * *

PRINTING MISTAKES IN I.P.

This refers to the letter to the Editor published in the *Eastern Pharmacist* June, 1989 issue regarding printing mistakes in I.P.

This printing mistake has already been corrected in Amendments issued by the authorities and published in IDMA Bulletin issue dated 31.3.88 by changing '54' to '27' in line 2 Appendix 7.4 page A-235, for Sulphuric Acid XN.

It would be worthwhile to publish all the amendments in a supplement so as to make them easily available to the users of I.P.

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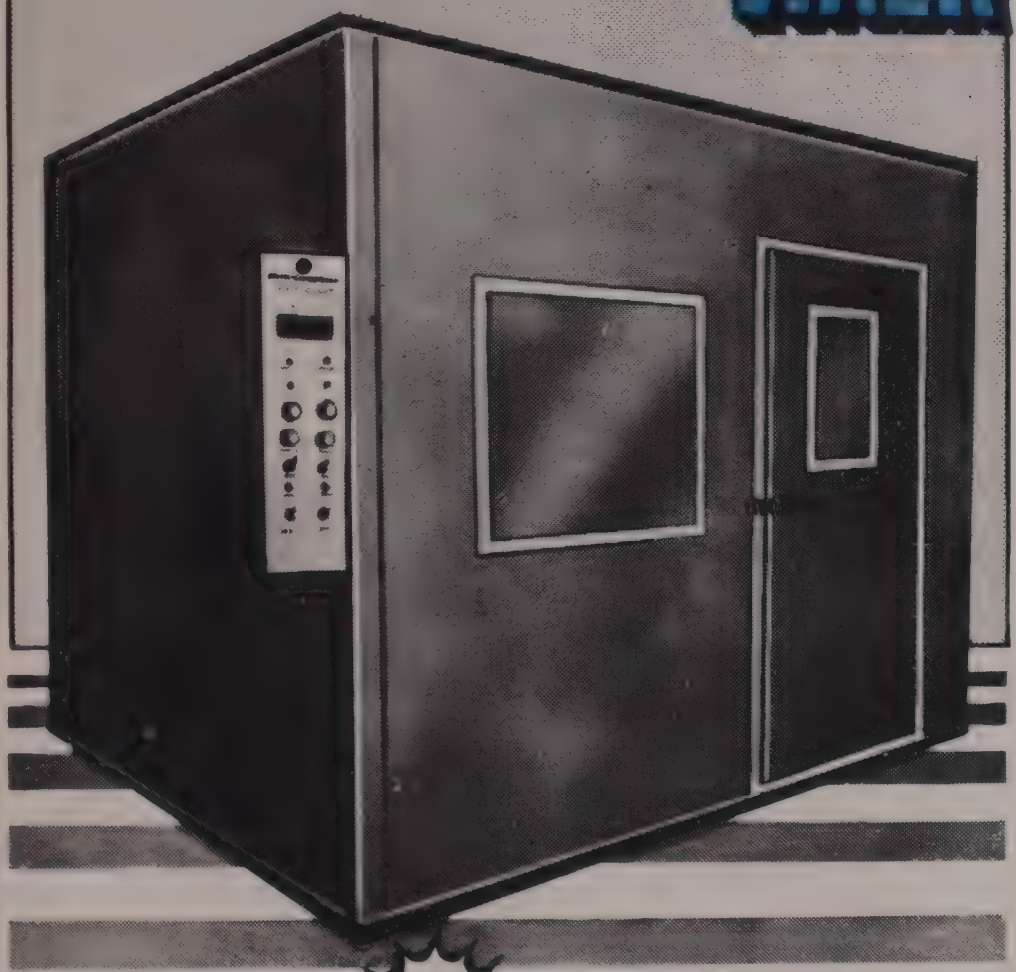

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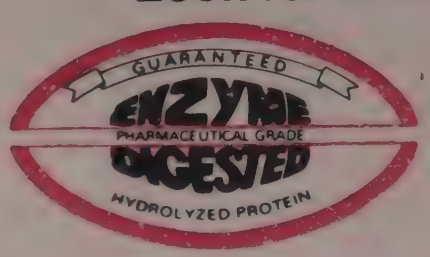

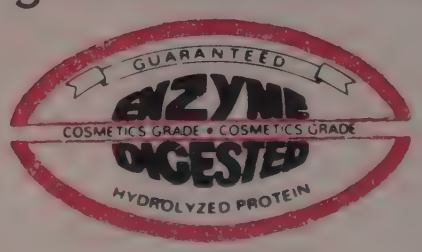

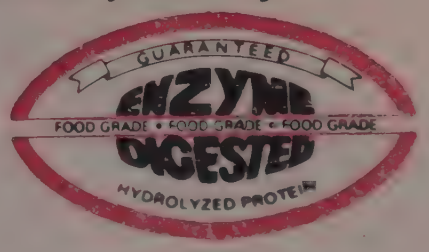

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In 1947 when India became independent there was hardly any controlling authority worth the name, the work having been entrusted to the Medical authorities in addition to their own responsibilities. But we have travelled a long distance since those days. While the total pharmaceutical production in 1947 was not more than rupees ten crores the latest figures available show that it has reached the figure of over Rs. 2690 crores now. Forty-two years ago the manufacturing units were confined to two centres of Calcutta and Bombay. Today the units are located in many centres spread over all states of the country. The rapid expansion and increasing production in drugs and pharmaceuticals have rendered it imperative that the Government should create a supervising machinery which can exercise effective control over production, quality and distribution of medicines.

Recently, Minister of State for Health and Family Welfare, stated in the Parliament that 13 out of 29 States and Union Territories in the country have full-time Drugs Controllers; sixteen States and Union Territories have only part-time Drugs Controllers. The Minister further added that the number of drug inspectors in the State and Union Territories was 664 as on April 1, 1988 as against 2,689 drug inspectors required as per the norms recommended by the Task Force on Spurious and Substandard Drugs. The norms were one drugs inspector for 25 manufacturing premises and one drugs inspector for 100 sales premises.

The Central Council of Health has meanwhile suggested setting up a high power group of State Health Ministers and Drugs Controllers for restructuring the drugs control machinery. This and other recommendations of the Council include those on guidelines for procurement, storage, distribution and withdrawal of drugs in the context of the existing shortcomings in the implementation of the Drugs and Cosmetics Act. The Council has identified the following difficulties and deficiencies in the implementation of the Drugs Act:

(i) Lack of adequate testing facilities in States (Only four States have full-fledged laboratories and 10 have facilities only to test non-biological drugs).

(ii) Lack of adequate Staff in the Drugs Control Directorates of the States and the Centre. (There are only 664 inspectors in the country as against 2,689 recommended).

(iii) Lack of effective action against manufacturers of Sub-standard/Spurious drugs. (Partly due to inadequate staff, testing facilities taking punitive action), and

(iv) Lack of effective mechanism to recall drugs reported to be not of standard quality, especially in emergency situations.

In majority of the Indian States even today Director of Medical Services is holding the charge of the Drug Control Administrations. Some of the States and Union Territories are not meeting the minimum statutory requirements of the Drugs & Cosmetics Act of 1940. As stated by the Minister of Health there are only about 664 drugs inspectors in the country. Maharashtra with the oldest Drugs Control Department with the largest number of manufacturers of drugs and pharmaceuticals have about 60 inspectors, headed ironically by an IAS officer with no pharmacy background. Only few States have pharmaceutically qualified Drugs Controllers. How is this small force of controlling authority with no technical background do any justice to the job passes our comprehension. It is too much to except for the present set up to seriously supervise the production, quality and distribution of drugs and pharmaceuticals when the industry and retail outlets have expanded tremendously and almost every year new plants are coming up by the dozens and thousands of retail outlets are opened which need close vigilance.

We have therefore to repeat what we have been saying all these years that in our view the Union Government should take the earliest steps to create separate Drugs Control Directorates in the Centre and in the States with required number of inspectors and thus provide for the recruitment of educated, trained and active pharmacists as Drugs Controllers and inspectors who will keep an observant and close eye on production, quality and distribution of drugs all over this vast country. Similarly testing laboratories in all States should be established with adequate technical staff to test the drugs.

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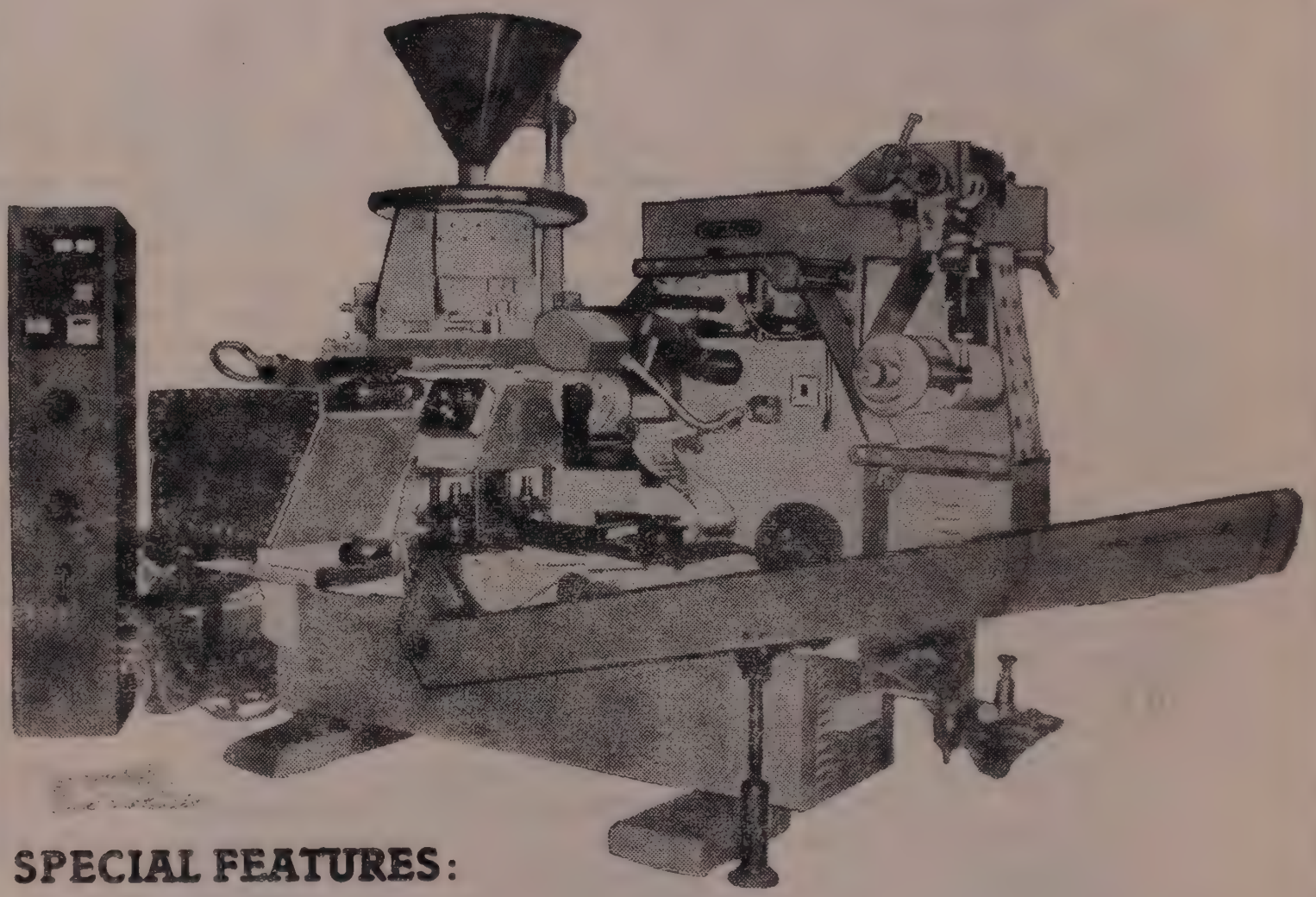

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Topical Comments . . . Dhanwantri

BANNED DRUGS RECALL

Time and again many voluntary health agencies and News Media have been pointing out availability and sale of drugs banned by the Government. It is true that many cases of such sales occur often. Recently there was a furore even in the Parliament over the fact that certain steroidal drugs with possible misuse as an abortifacient, certain depot therapy preparations which were banned earlier were available in chemists shops and were even being sold. While number of such drugs on the banned list may not be very large so far, there is another kind of banning of drugs seen of late. This pertains to regular announcements of banning for sale of sub-standard/misbranded drugs giving details of product name, manufacturer, batch No. and other details. With as mahy as 9000 manufacturers in the country, it is now humanly impossible for any one to remember such long lists. The mechanism of flow of such information is also not very spread out, considerably slow and ineffective.

This raises moral, ethical as well as professional questions. Is it not the duty of the manufacturer to see that such products banned for sale are duly withdrawn from the market? Or is it *only the manufacturers duty* to see that it is effectively withdrawn? What are the roles of the Governmental enforcement agencies, wholesale dealers and retail chemists in this regard? What kind of system is required in this regard? It is truely a grey area as it stands today, with no machinery or mechanisms mentioned in the drugs and cosmetics rules. The Drugs enforcement agencies wash off their hands after signing the statements or circular informing banning of drugs.

This question became highlighted during the recent happening related to banning of blood products by the Health Ministry. One of the manufacturers M/s. Albert David Co. is reported to have told that it was "Physically not possible to withdraw all the stocks with in a short period". Reasons cited were presence of large number of retail Chemists who may be having stocks, difficulty in reaching each one of them, slowness of communication etc. All these are true if such withdrawals of stocks of banned products are not taken seriously, and one is not ready to spend the amount of money required to speed up the process. Dhanwantri would believe that unless individual Retailer receives a note to withdraw from sale such banned products, giving details of where to deliver the stocks, how to collect reimbursements etc. nothing concrete would emerge. Due to the very nature of announcements publicity in electronic media and press may just inform the retailers *but do not force them to act.*

Dhanwantri does not agree with either the manufacturers or the Government for their present roles in such recalls. If a good invoicing system exists, giving in each invoice B. No. of drugs sold a little extra work by the manufacturer or the wholesaler can bring out a list of retail chemists who can possibly have stocks of the banned drug. What follows should be a systematic communication through the medical reps/sales boys/ cash collection boys to these retails to ensure physical removal of left over stocks from each retailer. Those companies or wholesalers who have computerised their invoicing and sales would find such work very easy if a suitable programme is written. This should not be very difficult. At the same time with ever increasing trade out lets for drugs and pharmaceuticals, Dhanwantri feels that all Drug Control Departments should start using a Computer facility. Such facility till the time each Drug Controller can get one of their own could be loaned, leased or borrowed from innumerable Govt. Agencies who have them already now. Then into a suitable programme list of all the licenced retail and wholesaller outlets under their control could be put. Whenever a circular regarding banning for sale of any product is to be issued, the computer could be asked to bring printouts of such circular to all of them and get them mailed quickly. Each Drug Inspectors whenever they go on inspections of sale premises should specifically check for banned items.

The Whole question of Recall of Drugs vis-a-vis present situation and D&C Rules needs a fresh look. Who would bell the cat ?

Safe Cough Ingredient

Readers may be aware that FDA was reviewing many OTC products since 1972. It has now declared that only one ingredient is safe and effective for use in non-prescription cough and cold medicines to help loosen phlegm, according to a recent standard published by the Food and Drug Administration. All other expectorant ingredients about 20 in all—must be taken off the market.

The one useful ingredient guaifenesin (pronounced gwy-uh-FIN-uh-sin) is a chemical compound that increases sputum or phlegm volume, makes it less sticky and makes it easier to cough up. Guaifenesin is the expectorant ingredient most widely used by makers of non-prescription cough and cold medications, including Benylin Expectorant, and Vicks Formula 44-Multi Symptom Cough Mixture. It also is approved as a prescription drug for use by patients with stable chronic

bronchitis, to help loosen phlegm and to thin bronchial secretions.

In announcing its regulations on over the counter recently (OTC) expectorants FDA said it is also requiring that the following warnings be included on labels of these products :

1. Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema, or when cough is accompanied by excessive phlegm, unless directed by a doctor.
2. A persistent cough may be a sign of a serious condition, If cough persists for more than one week, tends to recur, or is accompanied by fever, rash or persistent headache, consult a doctor.

Claims such as the following will be permitted on labels:

Helps loosen phlegm (sputum) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes and make coughs more productive.

FDA has also proposed ingredients given below as safe and effective for use in Over-the-counter medications to relieve certain allergy sysmptoms.

Antihistaminics (*to relieve runny nose and sneezing*);

—Bromopheniramine maleate, Chlorcyclizine HCl., Chlorpheniramine maleate, Dexbrompheniramine maleate, Dexchlorpheniramine maleate, Diphenhydramine HCl, Doxylamine succinate, Phenidamine tartrate, Pheniramine maleate, Pyrilamine maleate, Thonzylamine HCl., Triprolidine HCl.

Decongestants (*to relieve stuffy nose*):

—Phenylephrine HCl., Pseudoephedrime HCl., Pseudoephedrine sulphate.

Topical use Decongestants:

—1-Desoxyephedrine, Ephedrine, Ephedrine HCl., Ephedrine sulphate, Racephedrine sulphate, Racephedrine HCl., Naphaxzyline HCl., Oxymetazoline HCl., Phenylephrine HCl., Propylhexedrine, Xylometazoline HCl.

Formulators beware, don't rush to claim that your formulations containing these are FDA approved. With mansoon and season change can we hope for a freer nose?

The Last Pill !

The announcement that the 1989 Indian Pharmaceutical Congress will be held on 16th, 17th, and 18th December 1989 gladdens that there are people who act on Dhanwantri's writing (ref. Topical Comments, Jan '89 issue). Can Dhanwantri hope that his other musings are also getting similiar attention?

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Current Status & Problems Of Pharmaceutical Industry

Dr. S. Agarwala
President, Organisation of Pharmaceutical Producers of India.

The Indian pharmaceutical industry is a relatively small industry, just about the size of a single large company in the private or public sector in terms of investment and production. This is a reflection of the small size of the pharmaceutical market which is about 2% of the world market, although we have 15% of the world population.

However, with a population of around 800 million, which is projected to reach 1,000 million by 2,000 A.D., India is one of the largest potential markets for pharmaceuticals in the world.

Among developing countries the Indian pharmaceutical industry is already a leader in terms of the wide range and high quality medicines it produces and its capabilities to manufacture high-technology medicines right from basic stages. Some of the leading Indian companies have also become multinational by setting up joint ventures abroad and exporting technologies, management, technical skills and products to other developing countries. Thus, the importance of the Indian industry and the regulatory policies affecting it lies not only in terms of its expanding role, but, equally, in the influence which Indian policies tend to exert over other developing countries wanting to develop their own national pharmaceutical industries.

Paper presented at the joint meeting of IDMA and OPPI with Shri. M.S. Gill, Secretary Dept. of Chemicals and Petrochemicals, Ministry of Industry, on 2-3-89 reproduced from IDMA Bulletin.

Industry's Key Role

In the last 41 years of Independence, the pharmaceutical industry has played a key role in raising the general health standards of our people by making available a wide range of preventive and curative medicine – from simple headache pills to sophisticated antibiotics and complex steroid compounds.

Its pattern of production and growth conform to our national priorities and requirements. The industry operates within the overall framework of the Government's industrial and other policies and is today in the front rank of India's science based industries and contributes substantially to our national economy. The organised sector of the industry, consisting of wholly Indian and international companies, has placed a major role in promoting and sustaining this development.

Notwithstanding its sophisticated technology based nature, the pharmaceutical industry in India is relatively small in size, investment and production, as compared to other industries. Total investment in the industry today is around Rs. 750 crores. Production of bulk drugs and formulations in 1987-88 was Rs. 480 crores and Rs. 2,350 crores respectively. Although these figures represent a several fold increase over the level of production four decades ago, the growth rate has not kept pace with our national needs reflected in the rising demand.

The NCAER has estimated that drug production in the country has to increase at a cumulative rate of 14.4% per annum from 1980-81 onwards if the projected demand for medicines was to be met. As against this, growth rate in production was 9.1% during the Sixth Plan period and is expected to be 8-9% during the Seventh Plan. It is anticipated that the strengthening of the health infrastructure and wider coverage of population by expanded health services may result in an additional 4-5% growth in demand during the Eighth Plan. A growth rate in production of 12% is envisaged for the Eighth Plan.

Old Policy & Its Impact

There are several reasons why production of both bulk drugs and formulations have not increased to the extent they should have. One of the main reasons was the 1978 drug policy. Reservation of drugs for manufacture by different sectors under this policy, the brand-generic controversy which led to a stalemate in registration and introduction of new drugs, problems relating to pricing, import policies, canalisation of imports and other constraints adversely affected growth. Several provisions of the drug policy were either not implemented or only partially implemented.

Profitability Trend

Year	Profit before tax as % of Sales
1969-70	15.47
1974-75	10.7
1977-78	11.7
1980-81	8.8
1982-83	7.5
1983-84	6.7
1984-85	5.8
1985-86	4.5
1986-87	3.4

Source:
1969-70 – Hathi Committee Report
1974-75 – RBI Bulletin (covers drugs & non drugs) to 1980-81
1982-83 – NCAER Study to 1983-84
1984-85 – A.F. Ferguson Survey
1985-86 – Industry Estimate to 1986-87

The second major reason was the 1979 pricing policy and the rigid and cumbersome manner in which it was implemented. The net effect of this policy was to keep drug prices artificially low, making manufacture of essential drugs unremunerative and forcing drug companies to move away from pharmaceutical manufacture to more profitable areas for survival. Profitability of the industry, which was around 15% on sales turnover in 1978-79, declined to just 3-4% in 1986-87 which was far below even the levels provided for in the pricing scheme (namely, 8% to 13% on sales).

Some companies were in the red and others were on the brink. The position was bad enough. But it was rendered worse by arbitrary and unfair decisions in respect of price fixation which led to an unprecedented number of litigations between the industry and the Government. Apart from the delays and ambiguities, a general feeling of insecurity also set in. This crisis of confidence led to a stalling of the industry's growth.

Shortage of several drugs led to higher imports to meet the domestic demand. And the irony of it all was that much of this import was avoidable, had anomalies in the licensing and pricing policy not come in the way of fully utilising the existing capabilities of the industry. In some cases protection given to the public sector through reservation pre-empted capacities from being created by others, while the former was unable to produce drugs reserved for it in adequate quantities. Consequently, there was a double loss to the nation – production loss due to inadequate production and foreign exchange loss due to avoidable imports.

New Drug Policy

It was against this background that the pharmaceutical industry greeted the announcement of a more rational, pragmatic policy in 1986 after long years of deliberations in the National Drugs and Pharmaceuticals Development Council and other forums. However, unfortunately, there were delays and procrastination in the implementation of these measures. While the broad principles of the pricing norms were spelt out in the policy, a revised price control order embodying these principles was announced only in August, 1987. The new norms for conversion and packing charge, without which formulation prices cannot be revised or refixed, were, announced 18 months thereafter but they will be effective from April 1, 1989. Assuming that the revised prices based on the new norms are approved in three months time, they will come into force say by mid-1989. Thus there is a time lag of two years between the announcement of the policy and its implementation.

It is against this background that I wish to share with you my thoughts on two major areas of concern to the industry – Pricing and Technology. I do not propose to go into the details of the pricing scheme or to review the state-of-the art in drug technology.

What I do wish to dwell upon briefly is the more fundamen-

tal question of our entire approach to pricing and development of technology for the pharmaceutical industry.

Pricing

Let me first take up pricing. The new drug policy of 1986 and the new price control order of 1987 recognise two basic economic principles. First, price is a function of cost. Second, unless a reasonable return is assured, producers will not feel encouraged to increase production of essential medicines. Implicit in the policy is the assumption that a measure of price increase is inevitable in an inflationary economy. The extent of the price increase will of course depend on the magnitude of the cost escalation that has taken place. In my view, it is unrealistic to expect a general reduction in drug prices in an inflationary economy marked by alround cost increases. There is no strange alchemy that can transform high costs into low prices. But because of the rigid price control price rise has been the minimum in pharmaceuticals as compared with other commodities and even other price-controlled commodities. This is illustrated below:

Wholesale Price Index

	All Commodities (Base 1970-71=100)	Drugs & Medicines (Base 1970-71=100)	All India Consumer Price Index (Base 1960=100)
1980-81	270.7	137.5	420
1981-82	277.1	154.5	457
1982-83	295.3	171.4	502
1983-84	321.7	189.2	558
1984-85	346.3	191.7	586
1985-86	359.3	197.4	638
1986-87	377.8	203.7	686

Cost of production in the drug industry, as in other industries, continues to escalate in an inflationary economy that rides on cascading input costs. Prices can only be checked, in the long run, not through price control, but through more competition, higher production, better technologies, economies of scale and cost reduction programmes.

Price Control – An Inter Industry Comparison

Industry under Price Control	Wholesale Price Index (Base 1970-71=100) 1986-87
1. Petroleum products	622.7
2. Coal	716.9
3. Electricity	564.6
4. Cement*	469.7
5. Fetilizers	288.8
6. Paper	392.6
7. Sugar*	401.1
8. Edible Oils	379.1
9. Drugs & Medicines*	203.7

* Cover both controlled and uncontrolled items.

I do not mean to suggest that it is not possible to check prices. It is possible to reduce prices provided the Government takes some bold new initiatives in a number of areas to help the industry free itself from the " high-cost low-growth" syndrome.

Automatic Price Adjustment

In my view the first step called for is to evolve a concept of automatic approval of prices based on self regulation by the industry within the broad guidelines or parameters laid down by the Government. Under the present scheme of pricing, embodied in the DPCO 1987, the prices of about 150 bulk drugs and formulations based thereon which, account for over 70% of the drugs marketed in the country in terms of sales, have to be approved by the Government. This involves scrutiny and approval of not less than 15,000-20,000 price applications.

This is an awesome burden on the Government for which adequate administrative machinery just do not exist. Even now there is considerable backlog of price revision applications pending with the Government. Manufacturers have not been able to obtain neutralisation of their rising costs for several years now and with declining profit margins the industry's growth has suffered. Delays in price approval also act as a major different to investment decisions. Furthermore price increases granted at long intervals also create the impression in the public mind that the increases are excessive.

A system of automatic price adjustment has several merits both for industry and government. Apart from the time saved in the approval process, industry can function under conditions

of greater certainty. It can plan better for the future, take decisions without fear of violating some complicated regulation and, generally, get on with the job of management. The government, by freeing itself from the administrative burden of routine price approval, can concentrate on the more important tasks of identifying priorities, evolving policy guidelines and planning the growth of the industry.

Price Decontrol

The second step is decontrol. About 30% of the products marketed in the country is at present free from price control. We should aim at progressively increasing this percentage to, say, at least 70 per cent by the end of the 8th Plan. By 1994-95 only medicines required for the Government health programme (Category I) may be under price control. And even these could be removed from price control during the 9th Plan period by which time the upsurge in production and competition would keep prices of all drugs under check far more effectively than administrative control. However, to ensure that no company makes excessive profit, a ceiling on profitability may be specified and every company must submit annual returns duly certified by auditors.

These suggestions may be considered radical or unrealistic against the background of a quarter century of rigid and almost total control on prices. But I have no doubt that this prescription is simple to administer and it will meet the overall objectives of the Government. It has the following distinct advantages.

1. Market forces will stimulate healthy competition leading to competitive prices which will be fair to both manufacturers and consumers.
2. Government will be free from the unnecessary administrative burden of having to fix the individual prices of thousands of products.
3. No company will be able to make excessive profit.

There is no need to fear that decontrol will lead to a spurt in drug prices. If one were to go by market responses and the experience of price control in our country, there is a greater likelihood of prices ultimately coming down by decontrol rather than by control. This has happened in the case of cement and sugar and there is no reason why it should not happen in the case of drugs, particularly because there are thousands of manufacturers – large, medium and small – operating in a fiercely competitive market. Studies made by the Economic Administrative Reforms Commission have shown that, over the 10-year period, 1970-71 to 1980-81, price increases in price-controlled commodities were much more than in non-controlled items.

National Policy for Taxations of Medicines

While on the question of pricing I must refer to a disturbing trend being witnessed in the country today. The Department of Chemicals & Petrochemicals is very keen that the burden of taxes and duties on medicines, which at present works out to not less than one-third of the prices consumers pay, should be reduced, if not eliminated altogether. It has already taken certain initiatives in this regard by exempting some essential and life-saving drugs from customs and central excise duties. However, some State Governments and municipal bodies are moving in the opposite direction. They have proposed new State and local taxes such as turnover tax, consignment tax, etc. in addition to State excise and sales tax. And what is worse, some State Governments want the manufacturers to carry the burden of these taxes by expressly prohibiting them from passing it on to the consumer. I would urge, in this connection, that since medicines are an essential commodity, a national policy for taxation of medicines should be evolved, in consultation with State Governments and the latter, including municipal bodies, must strictly follow these policy guidelines.

Technology-Key to Development

My second submission relates to technology. Technology is important for every industry but for the drug industry it is critical because the technology employed has a vital bearing on cost of production and the quality and safety of drugs produced. The record of the Indian pharmaceutical industry in terms of technology development is excellent. However, in the last few years, technology development seemed to have stagnated. The study by the NCAER identified significant gaps in drug technology. According to the NCAER, the industry presented a "varied picture containing a few bright patches amidst several dark spots". But it recognised that we have well-developed capabilities for the manufacture of a wide range of formulations and that there was no need to import formulation technology except sophisticated drug delivery systems. However, the NCAER emphasised that there was definite need for updating the existing technology and introducing new technologies for the manufacture of conventional and newer antibiotics, synthetic drugs in general, corticosteroids, vitamins, immunologicals and new drugs.

One area in which our technology is far below international standard is fermentation technology used in the manufacture of antibiotics, steroids, vitamins and enzymes. One of the major reasons for this is the absence in our country of R &D for improvement of microbial strains, fermentation techniques, down stream processing and recovery methods. For some antibiotics, our strains are only 30-40% as productive as the best in the world and the recovery levels are 10-15% lower. As a result, even assuming that input costs are comparable, the production cost of these antibiotics would be 75% to 100% higher than those of leaders in this area.

How to bridge the technology and production gaps economically, quickly and effectively should be one of our primary concerns if we are to regain lost ground and develop fast towards the goal of technological self-reliance and greater

production of better and economically-priced drugs.

It is this approach to self-reliance through choice of technology that has enabled Japan to emerge as world leader in technology in several areas. Even today, Japan is a net importer of technology on a massive scale involving heavy foreign exchange outlay. What Japan initially did was to follow a policy of defensive R&D. It concentrated on the assimilation, absorption and modification of acquired technology.

We have the third largest pool of scientific and technical personnel in the world who, given proper incentives and encouragement, would be capable of taking our industry forward in drug technology.

I believe that the best means of technology transfer is through collaboration – technical or financial. We need to keep our doors open to facilitate a continuous flow of technology even while developing our own indigenous technological competence through sustained R&D. Here is where OPPI and IDMA members can and are playing an important role – to innovate, adapt and modify technology transferred by their parent/associate companies. They have the capability to do much more in this vital area. They have the requisite technological competence and access to newer technology of their parent/associates abroad which has in the past benefited and will in the future benefit the industry as a whole.

However, I must emphasise that development of drug technology cannot take place in a vaccum. It presupposes an industrial culture and an environment in which innovation and enterprise are encouraged and rewarded. In this context, I welcome the recent decision of the Government to exempt from price control for five years drugs manufactured from basic stages by technology developed through indigenous R&D.

Conclusion

I have come to the end of my presentation. What I placed before you are some thought on two issues of utmost concern to our industry. There are several others which my colleagues will deal with in their presentations. The consensus that emerge out of our discussion needs to be formulated into concrete suggestions and recommendations. I am confident that our distinguished guests, Shri Gill and Shri Mathur, will carefully consider them and take appropriate decisions in due course.

Before I conclude I must acknowledge that in the last few years there has been a perceptible and progressive shift in Government policy towards the pharmaceutical industry. From rigid control and regulations the policy focus has changed to liberalisation and pragmatic measures for promoting growth and development.

I believe that the scheme of automatic price adjustment, coupled with responsible, self-regulation by the industry itself, will be a further step forward in this direction. It will foster mutual confidence and trust between the Government and the industry. We need to build bridges of understanding. There is no room for conflict or confrontation. Both the Government and the industry must work together in a spirit of cooperation and mutual trust so that the industry can effectively play the role society expects it to play. To make available medicines of the highest standard of quality and safety, in adequate quantities, at reasonable prices to all our people.

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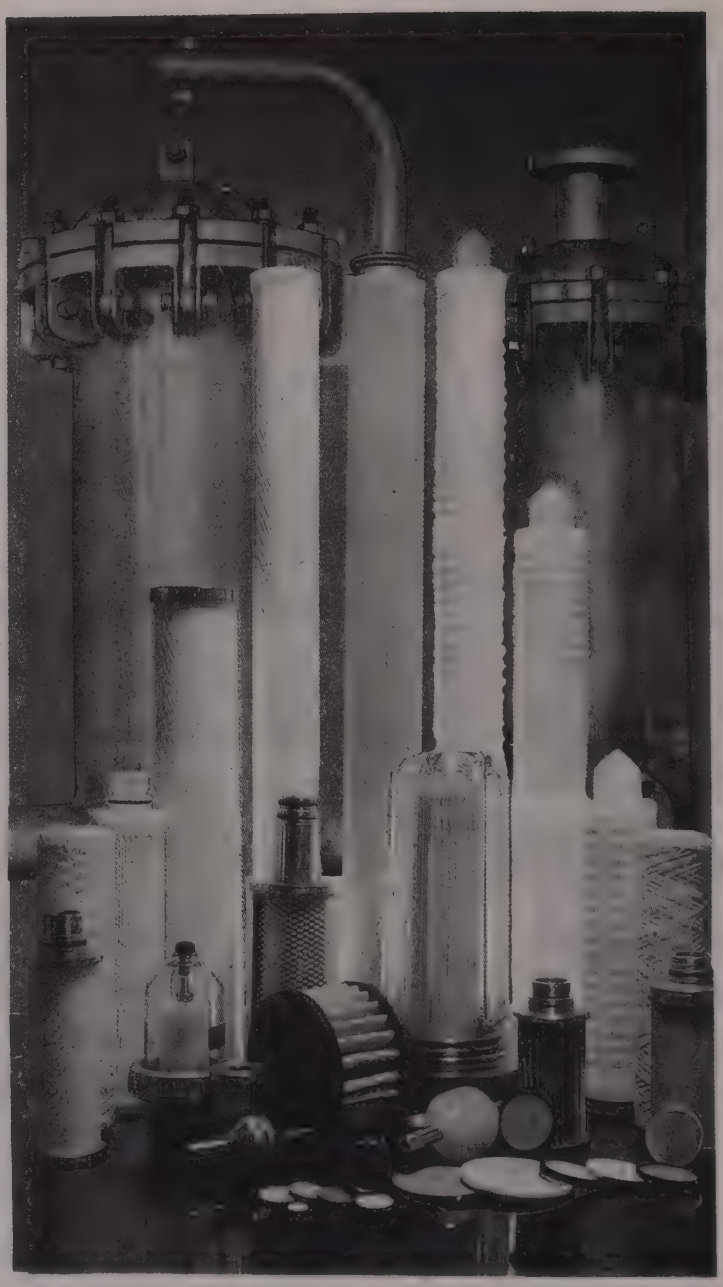

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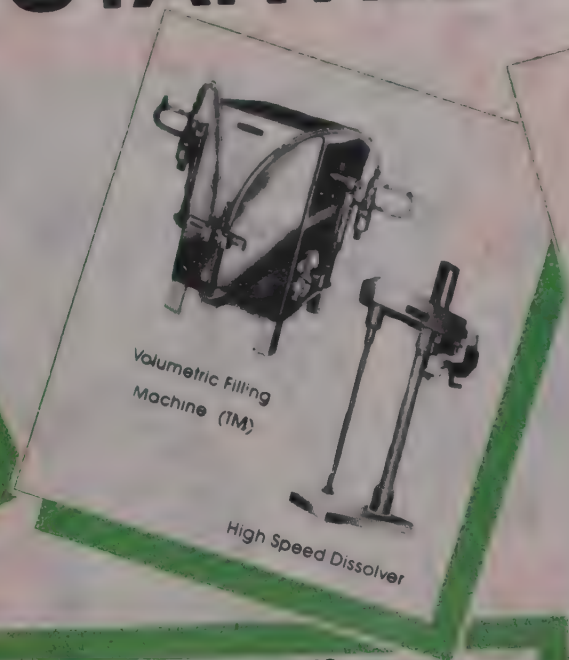
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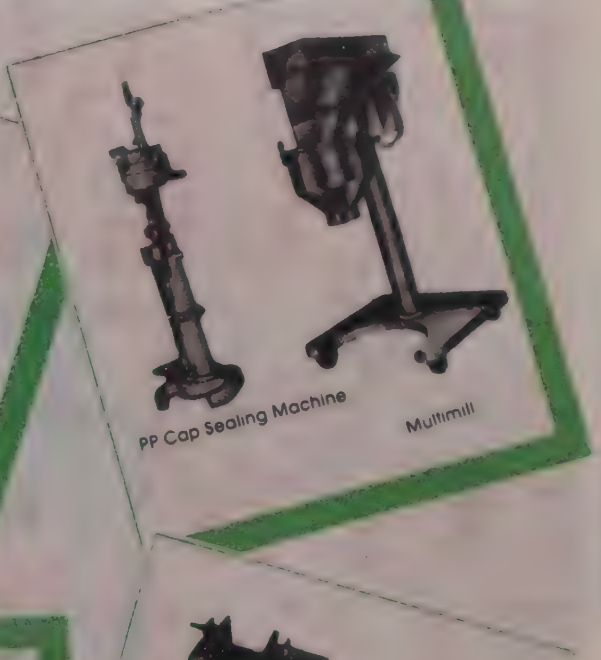
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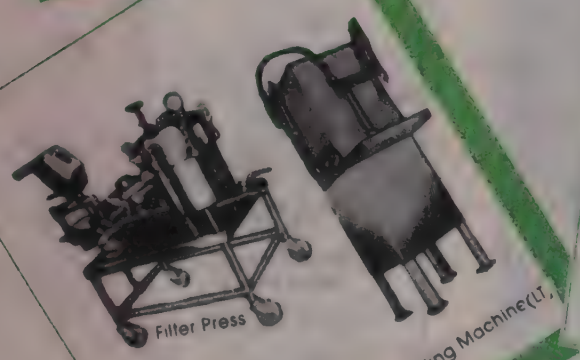
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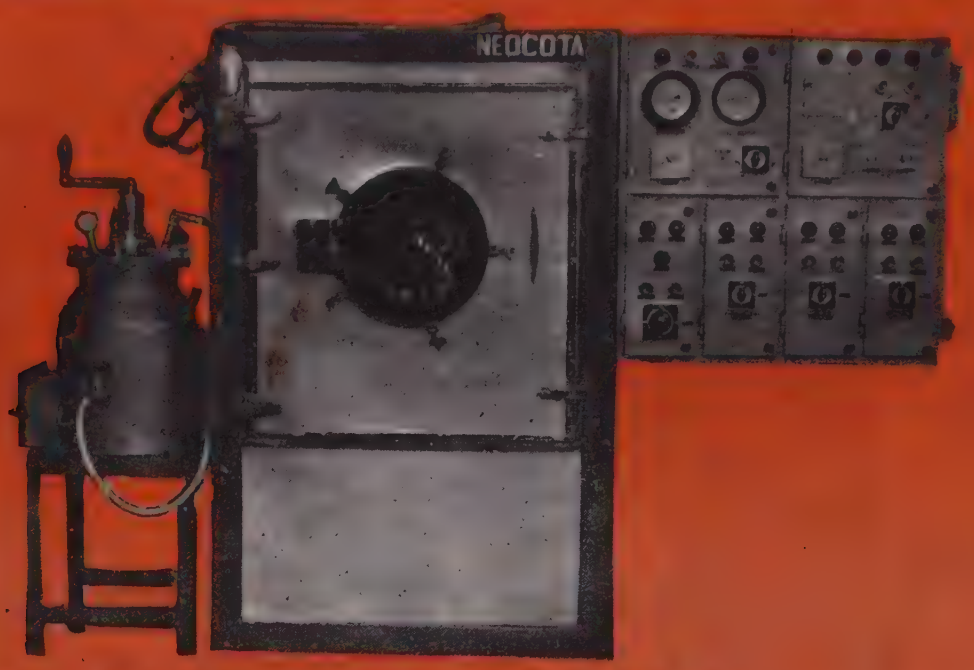

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SPECIFICATION

MODEL	NEOCOTA 24	NEOCOTA 36	NEOCOTA 48
Approximate working capacity (depends on tablet shape and density)	18 kilos	70 kilos	135 kilos
Pan Diameter	610 mm	915 mm	1220 mm
Pan Speed	12-30 rpm	3-17 rpm	5-15 rpm
Drive Motor (flame-proof)	1 HP×1440 rpm	1.5 HP×1440 rpm	2 HP×1440 rpm
Height	1500 mm	1700 mm	1850 mm
Floor space	2050 mm×750 mm	2250 mm×1300 mm	2460 mm×1350 mm
Weight (approx.)	1150 kilos	1460 kilos	1620 kilos
Exhaust Fan flow-rate	300 cfm at 6" water gauge	1200 cfm at 8" water gauge	2500 cfm at 8" water gauge
Exhaust Fan Motor	1 HP×2880 rpm	3 HP×2880 rpm	7.5 HP×2880 rpm
Hot Air flow-rate	300 cfm	1200 cfm	2500 cfm
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Aspirin Reveals Modern Face

For almost a century people have been reaching for the aspirin bottle to help ease their aches and pains. The drug continues to be the subject of intense clinical scrutiny and is still finding potential new uses. Drug information specialist, Steve Chaplin, MPS, reviews some of the more recent discoveries and wonders if this familiar drug is not shaking off some of its 'homely' image to take a greater role in the fight against problems such as heart attacks and cataracts.

The origins of aspirin are traced back to the 18th Century, when the Reverend Edmund Stone first tasted the bark of the common white willow. He noted that its bitter taste resembled that of cinchona bark, which was then used as an antipyretic and analgesic. Using the Doctrine of Signatures, he reasoned that a tree which grows in a damp area "where agues abound" would be useful for treating those very complaints.

Willow bark became popular as a substitute for the increasingly scarce cinchona bark and the active principle, salicin, was first isolated in 1829. this could be converted chemically to salicylic acid, an ingredient known to occur in some other plant species. In 1860, salicylic acid was synthesised chemically and, within a few years, synthetic sodium salicylate was being used to treat gout, rheumatic diseases and fever. But adverse effects, notably gastrointestinal intolerance, often limited the success of therapy. In an attempt to improve safety, a 40 year-old neglected discovery was re-examined. Acetylsalicylic acid had first been discovered in 1853 but had been shelved because its synthesis was so difficult. Chémists at Bayer developed better synthetic methods and the new compound, christened aspirin, was launched in 1899.

An early bottle of aspirin (c.1912). Courtesy Bayer UK

From that time, aspirin has been used widely as an analgesic, antipyretic and anti inflammatory agent. But interest in its wider applications grew in the 1970s with two, parallel lines of research. A possible link between aspirin ingestion and protection against myocardial infarction was observed in 1974, inspiring work which is only now bearing fruit. And the drug's mechanism of action was explained by Nobel prize winner Sir John Vane, revealing the complex effects of the prostaglandins and related compounds.

Prostaglandin Link

Prostaglandins are ubiquitous, often short-lived mediators derived from dietary fatty acid. They are synthesised by most cells in the body (red blood cells are one exception) but not stored. All Prostaglandins are therefore produced de novo on demand. In man, the major precursor of the prostaglandins is arachidonic acid, which is found in the phospholipid of cell membranes or as a part of other complex liquids. This is released by chemical, hormonal or physical stimuli and undergoes rapid metabolism by several enzyme systems. Prostaglandins and their congeners arise from the action of the enzyme cyclo-

oxygenase, which is inhibited by aspirin and other anti-inflammatory drugs. By contrast, the leukotrienes, a different family of fatty acids which is involved in inflammatory processes, are the result of action by lipoxygenases.

After oxygenation by cyclo-oxygenase, several classes of prostaglandins are formed (see figure 1 on next page). These are described by the nature of their chemical substitution (designated by letters-eg prostaglandin E) and the number of double bonds (designated by numbers - eg prostaglandin E2). Some of these compounds undergo further enzyme alteration to form thromboxanes and prostacyclin. All these chemicals are short lived mediators (their half-lives are measured in minutes) involved in many functions throughout the body, including inflammation, clotting and labour. Different tissues vary in the proportions of these different agents that they synthesise. For example, cells in the lung synthesise the complete range whereas platelets synthesise mainly thromboxane A2 and blood vessel walls produce mostly prostacyclin. This is an important difference because thromboxane A2 is a powerful vasoconstrictor and aggregator of platelets and prostacyclin inhibits platelet aggregation and causes vasodilatation.

Aspirin acts by acetylating irreversibly the key enzyme cyclo-oxygenase and various tissues differ in their sensitivity to this effect. Platelets are unable to resynthesise this enzyme, so a single dose of aspirin blocks prostaglandin synthesis - in particular thromboxane synthesis - for the 8-11 day life of a platelet.

Myocardial infarction

The inhibitory effects of aspirin on platelet aggregation are therefore apparent at doses which are very low (as little as 40 mg daily) compared with those needed for anti inflammatory activity or analgesia.

A recent comparative trial in 20 patients with recent myocardial infarction showed that a dose of 500mg on every third day reduced the elevated blood concentrations of thromboxane but had no apparent effect on prostacyclin levels.

But aspirin is not the complete answer to preventing thrombosis. Research in animals has shown that aspirin induced inhibition of thromboxane synthesis can be overcome by adrenaline. People in whom endogenous levels of adrenaline are high -as in smokers or people under stress -could therefore benefit less from aspirin.

These findings inspired research into the prophylaxis of thrombotic diseases such as myocardial infarction, unstable angina and stroke. In the United States, a review of 14,000 patients who had suffered a myocardial infarction found that, compared with a control population who had not had a heart attack, they had taken less aspirin. In the U.K., the first placebo-controlled study of aspirin in preventing second heart attacks reported a 25 percent reduction in mortality, although this did not reach statistical significance. Research continued and, by 1980, a review of ten separate trials involving 10,000 patients showed that aspirin reduced mortality and morbidity among infarct patients.

There has been similar success in secondary prevention of other vascular diseases. A six-year UK trial has now shown that, in patients with a history of ischaemic stroke or transient ischaemic attack, the risk of vascular events, including a major stroke, was cut by almost a fifth after prophylaxis with 300mg or 1,200mg of aspirin daily. The higher dose was no more effective but did cause more adverse gastrointestinal effects.

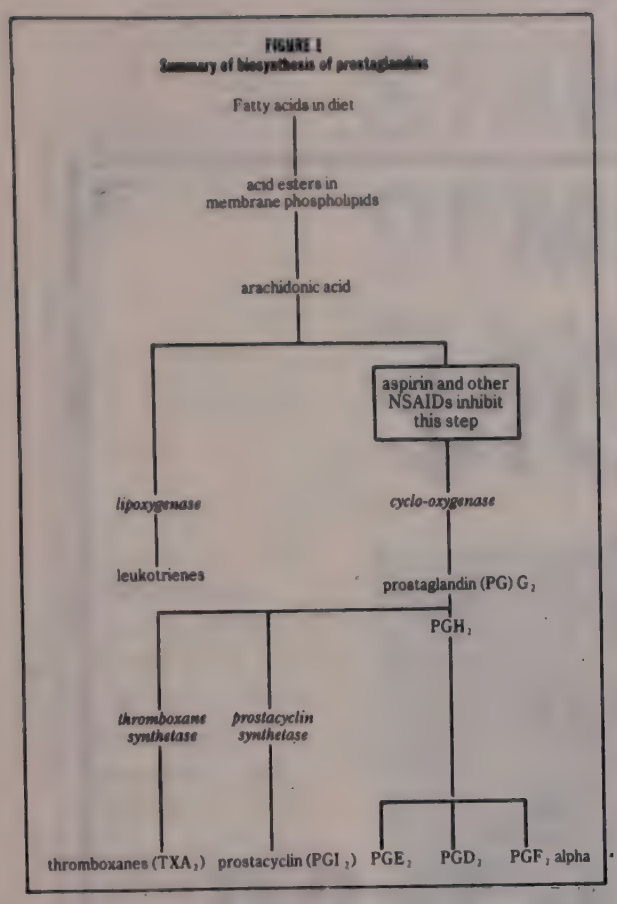
Finally, conclusive and convincing evidence was provided in 1988. A new statistical analysis of 25 placebo-controlled clinical trials showed that fatal vascular events-for example, stroke, heart attack-were reduced by 15 per cent after prophylaxis with aspirin or other antithrombotic agents and that non-fatal events were cut by almost a third. There is now little doubt that aspirin is effective in preventing vascular events in people who are at increased risk. The optimum dose still needs to be decided but, at the moment, many favour 75-300mg daily.

By contrast, aspirin has proved less useful as primary prevention-preventing heart attacks in apparently healthy people-and major trials have produced conflicting results. The most recent of these involved healthy doctors on both sides of the Atlantic who took doses ranging from 325mg on alternate days to 500mg of aspirin daily for five-six years. In America, the risk of myocardial infarction was reduced by 47 percent but the British proved less responsive-there was no reduction in fatal or non-fatal heart attack. The benefits of aspirin in primary prevention can only be gained at some cost. It has been estimated that 850 healthy people would have to take aspirin for five years to prevent just one death from myocardial infarction.

Nonetheless, aspirin has found a role in treating myocardial infarction in the acute phase. The influential ISIS-2 study demonstrated the efficacy of intravenous streptokinase in reducing death from heart attack. But it also showed that a month's treatment with aspirin (160mg daily) was equally effective, reducing the risk of vascular deaths by 23 per cent. The two drugs in combination produced an additive effect, cutting the risk of death from vascular events by 42 per cent. Similar effects are achieved with other thrombolytic agents such as plasminogen activator (alteplase).

Other uses

Aspirin's vascular actions may also underlie its possible effects in the prophylaxis of migraine. Some evidence has shown that a dose of approximately



75mg daily substantially reduces the number of migraine attacks. In one study, the frequency of attacks was cut 10-17 fold during 18 months' prophylaxis. There is, however, other evidence from a double blind trial that aspirin has no effect although this, too, was small. Further work is needed to clarify this conflict.

Unexpectedly, there is growing evidence that aspirin may protect against some cases of cataract. Again, the underlying mechanism appears to be acetylation, in this case of proteins called crystallins which occur in the lens. There is some epidemiological evidence, although it is contradictory, that the long-term use of aspirin may be associated with a lower incidence of cataract. But this protective effect appears not to occur with diabetics, in whom cataract is common.

Clinical trials are currently underway looking at aspirin in the management of preeclampsia. This syndrome of severe hypertension during the second half of pregnancy causes placental ischaemia and infarction, resulting in intrauterine growth retardation by asphyxia and nutritional deprivation of the foetus. The underlying mechanism of pre-eclampsia appears to be the obstruction of uterine arteries by fibrin and thrombi. The potential benefits of preventing platelet aggregation with aspirin are therefore clear and preliminary evidence, based on an open study in 42 women, is encouraging. In this group of women, only eight of a total of 84 previous pregnancies had resulted in live births and, of the pregnancies which proceeded past the first trimester, 79 per cent had signs of growth retardation. All the babies who eventually survived were abnormally small. Yet, after prophylaxis with 75mg of aspirin daily from the first or second trimester, 88 per cent of 38 subsequent pregnancies proceeded to live births with growth retardation occurring in only 29 per cent. Similar results have been reported from Holland using a combination of aspirin with another antithrombotic agent, dipyridamole. However, despite encouraging findings, both groups caution that their data need confirmation in a controlled trial before aspirin can be used routinely for pre-eclampsia.

Adverse effects

The findings of the latest research on aspirin have been positive. But can these gains be achieved without the risk of adverse effects?

The risk: benefit ratio is far from clear for healthy people in whom primary prevention of vascular disease is contemplated. Adverse effects are uncommon and largely confined to the gastrointestinal tract but the frequency of haemorrhagic stroke may be increased. In spite of the large scale of the studies reported to date, this event is so rare that it remains uncertain whether this represents a substantially increased risk. Gastrointestinal symptoms are uncommon at doses of 300 mg daily or less and can be reduced further by using an enteric-coated formulation. In a large American study, nearly a quarter of subjects taking low-dose aspirin reported gastrointestinal discomfort, but a similar proportion given placebo complained of the same symptoms, emphasising the high background incidence of minor gastrointestinal upsets. Peptic ulcer or non-fatal gastrointestinal bleeding were increased by aspirin in doses of 300-500mg daily although the number of patients affected was relatively small. By contrast, the number of migraine attacks was apparently reduced.

Aspirin does, however, present a more serious threat to the elderly, who are more susceptible to the gastrointestinal effects of anti-inflammatory drugs. A recent case control study in Nottingham found that people aged over 60 years old were 2-3 times more likely to be admitted to hospital with bleeding ulcers if they had taken aspirin. This effect was also observed with other anti-inflammatory agents, which together with aspirin accounted for a third of bleeding ulcers in this age group. No such link was found with paracetamol. It is, however, unclear whether aspirin causes the ulcers themselves or if it causes existing ulcers to bleed. It is estimated that, throughout the UK, aspirin may account for 20 cases of bleeding ulcers each week, an adverse effect which carries a 10 per cent mortality.

On balance, the continuing research with aspirin is revealing a drug with unrealised potential but with unrecognised toxicity. Its use as a household analgesic has been so prevalent that it was only recently challenged by links with the rare children's disease Reye's syndrome. The status of aspirin is now being elevated but, at the same time, it may be shedding its homely image. Instead, paracetamol offers an effective and apparently safe alternative for everyday use.

Just as the prostaglandins are discovered to be important mediators in almost every cell in the body, so will the value of aspirin continue to develop. In the future, we can expect to reach a greater understanding of the effects of lower doses with increasing margins of safety.

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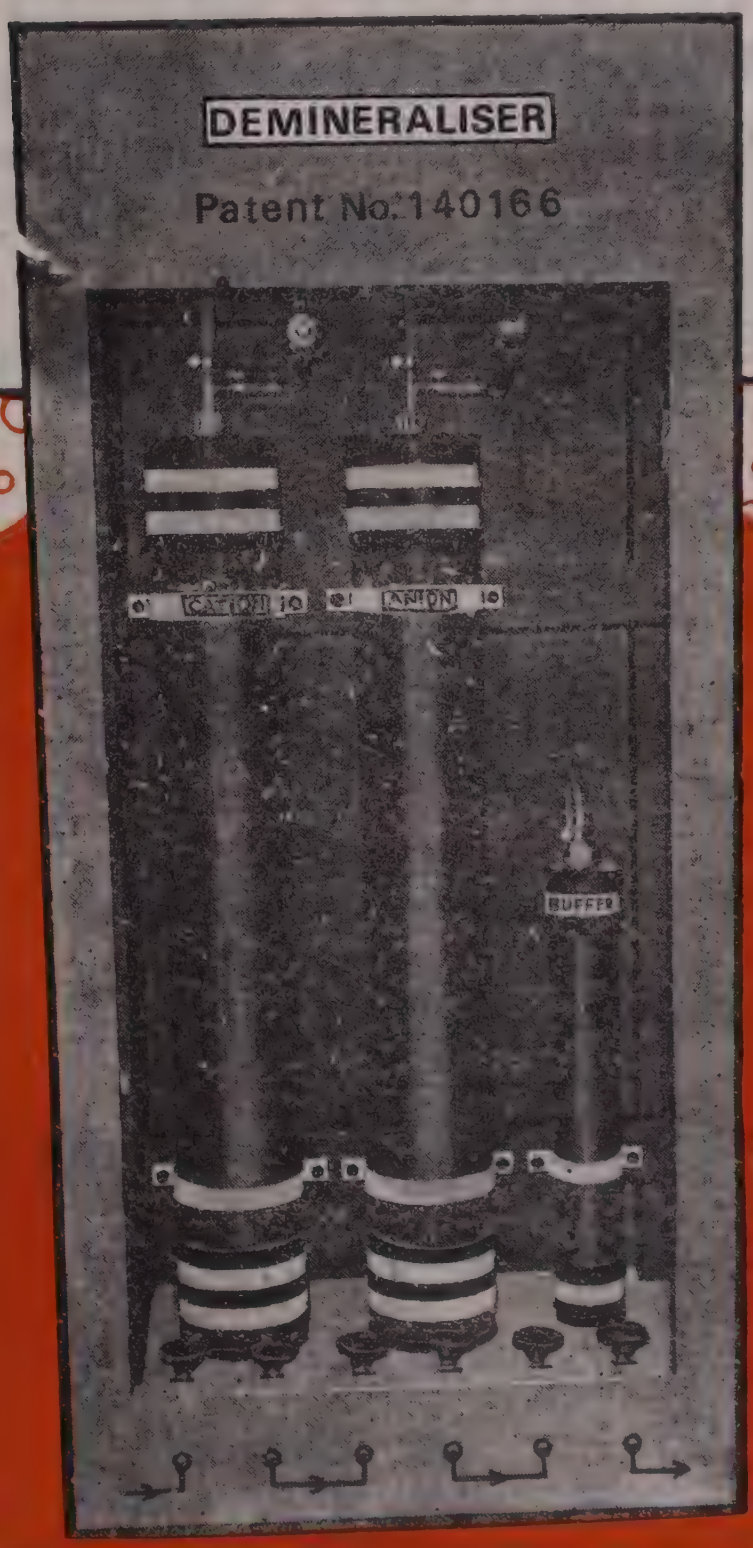

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With Special Reference to Various Quality Control Measures in the Manufacturing of Eye Drops

GOOD MANUFACTURING PRACTICES IN THE PREPARATION OF OPHTHALMIC DRUGS

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Division of Pharmacology
Dr. Rajendra Prasad Centre for Ophthalmic Sciences ,
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Ansari Nagar, New Delhi - 110 029.

Summary

GMP is the assurance that a product can be manufactured reproducibily to meet the labeled claims for safety and efficacy. It provides a sound base data on a product so that determinations can be made during the manufacturing process to indicate whether or not the end product will properly perform. Since, the process is under strict control there should be fewer batch rejections and rework required. Finally the GMP is to maintain strict process control within process testing. The present article summarises the important parameters which are of vital importance and must make part of GMP in the manufacturing of eye drops. Keeping in view the quality assurance an attempt has been made to develop methods of manufacturing of eye drops at this apex organisation. Various quality control measures eg. osmalality, pH, use of absorption spectra, microbiological testing for commonly used ophthalmic drugs have been included for in process testing and to produce ophthalmic drugs of high quality.

Introduction

Good manufacturing practice (GMP) Programme provides a high degree of assurance, that a specific process will consistantly produce a product meeting its pre-determined specifications and quality attributes. GMP are based on the concept that quality, safety and efficacy must be built into the product. In the early developmental stage attention must be given to designing the best product within realistic constrains and current state of art. The various factors which effect the quality of the product includes (a) raw materials (b) packaging components (c) Equipment and the premises of manufacturing (d) staff (e) manufacturing procedures (f) in process testing and specifications and (g) finished product specifications.

Another principle of GMP is that at each step of manufacturing it must be ensured that the finished product will meet all the criteria laid down for the end product. The overall objective must be to provide batch uniformity and reproducibility to assure safety and efficacy of the drug. It would be desirable to

establish the product characteristics that are measurable parameters by which we can identify the product. Each drug has a characteristic test and a specification that is validated. So that a test result for a routine procedure batch will indicate whether or not the batch conforms the prescribed limits.

Various Parameters Which Are Of Vital Importance In The Quality Control Of Ophthalmic Drugs

Tonicity of ophthalmic solutions (Osmolality) : Lacrimal fluid is isotonic with blood having an isotonicity value approximately the same as that of a 0.9% sodium chloride solution. As a generalization it may be stated that an ophthalmic solution isotonic with lacrimal fluid causes less discomfort than the one which is hypotonic or hypertonic. It may indeed, have a soothing rather than an irritaing effect on the eye.

When a solution and its solvent are separated by a semi-permeable membrane, the solvent diffuses to the solution side by osmosis when enough time is allowed for equilibration. To stop this diffusion, osmotic pressure must be applied to the solution side. Osmotic pressure is directly proportional to the number of particles in solution regardless of size, shape, weight or charge. The measurement of the total number of particles in solution is called osmometry. Osmolality is the measure of the total number of particles in solution and is expressed as osmol/kilogram or milliosmol/kilogram (mosm/kg). Concentration of substances capable of exerting osmotic pressure is expressed in terms of molality or osmolality.

In order to have a clear understanding about the tonicity, it is necessary to understand that there are four properties of solutions that depend only on the number of particles in the solution. They are osmotic pressure elevation, boiling point elevation, vapor pressure depression and freezing point depression. The method generally used to measure the osmolality of ophthalmic preparation is that of freezing point depression which can be measured quite readily with a fair degree of accuracy. At our centre a Semiautomatic high sensitivity micro osmometer (Osmette, model 4001, precision systems) is being use for this purpose which provide digital readouts of the results expressed in milliosmol units.

The osmometer is able to control the environment and conditions under which a sample solution, is cooled and frozen, so that measurement of the freezing point may be made repeatedly, to approximately $\pm 0.001^{\circ}C$. Since one milliosmol (mOsm) (a convenient unit of concentration) per kilogram of water change in concentration will cause a change of $.0.001858^{\circ}C$ in the freezing point, it is possible to measure concentrations very precisely. Table 1 shows the various eye drops and corneal preservative mediums for which osmolality is determined at this centre.

Hydrogen ion concentration (pH): The hydrogen ion concentration of an ophthalmic solution may have a considerable effect on the therapeutic action of the solution, the comfort of the patient and the stability and solubility of the active constituent of the solution. The greatest comfort (least irritation) for the patient is expected to be found at the normal pH, approximately 7.4 of lacrimal fluid but comfort is usually adequate in the pH range of 6 to 8. Therefore, all ophthalmic solutions must fall within an acceptable pH range. Formulations below pH 4 or above pH 10 are likely to cause severe irritation or even damage to external ocular tissues. Increases in alkalinity are more easily tolerated than increase in acidity.

At our centre, pH of all the ophthalmic preparations is measured using a computerised digital pH meter. A fixed pH range has been established as our internal standard and deviations of $\pm$ 2% only are permissible (Table 1).

Sterility : Sterility of ophthalmic preparations is of primary importance in drug manufacturing since introduction of pathogens into the eye has the potential to precipitate a serious infection. Contaminated solutions have been the cause of corneal ulcers and loss of eye sight. One of the most frequent contaminant is Pseudomonas aeruginosa. It can cause complete loss of sight within 24-48 hrs. As Pseudomonas aeruginosa is a common inhabitant of human skin, the contaminating organisms could come from the physician, the nurse, the patient or the air. Other common organisms responsible for infections such as Bacillus subtilis and Aspergillus fumigatus are also known to contaminate ophthalmic preparations. Viruses can also contaminate ophthalmic preparations. They are destroyed by autoclaving. It was found that use of one bottle of virus contaminated tetracaine caused as many as 42 cases of epidemic conjunctivitis (Deardorrf, 1980). Though most manufacturers give instructions that the preparation must be used within a month of opening, it is safer to discard all ophthalmic preparations within 1-2 weeks of opening the bottle (Reigelman and Vaughan, 1958).

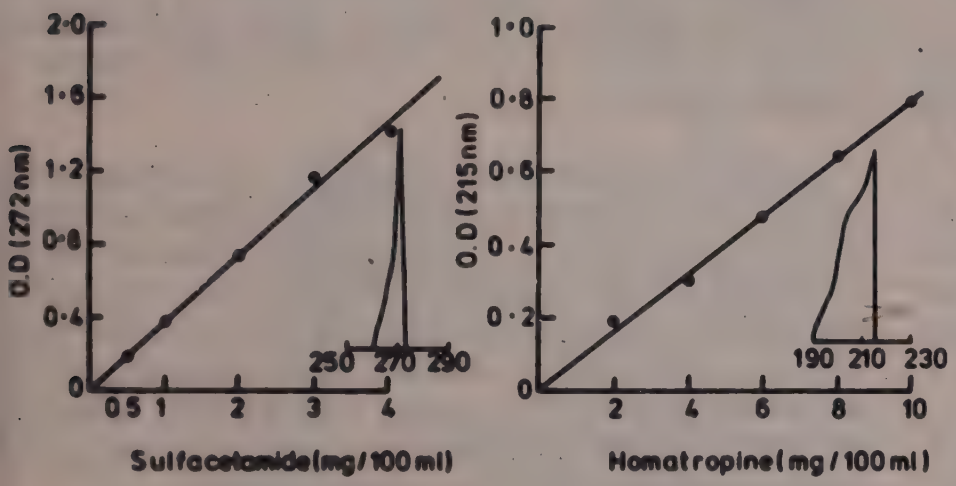
Therefore clear directions must be printed on the bottle with dropper to the effect that the tip of the dropper must not be left uncovered after use, should not touch any surface and must not touch the patients eye lashes. If possible hands must be washed with soap water before administering any eye drops.

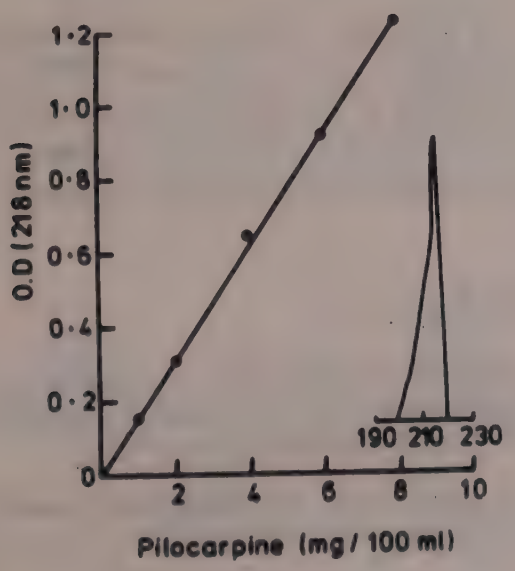
Stability : Drug stability is an important consideration in drug manufacturing Various factors that effect stability are pH, temperature and exposure to light. Sometimes pH of the drug has to be altered to preserve its shelf life even if it is not the ideal pH for the eye. In such case the drug must be compounded with a weak buffer. This allows the bicarbonate buffer in the tears to bring the pH back to normal so that the drug will be less irritating. An example of such a drug is pilocarpine which being a weak base is absorbed most readily at an alkaline pH (Sieg and Robinson, 1977) but pilocarpine is dispensed in an acidic pH to preserve it's shelf life. The stability of drug is also decreased by oxidizing agents such as light; keeping the drugs in dark will increase their shelf life. When bottle is opened more air is introduced, causing oxidation to occur more rapidly than in the sealed container. Antioxidants such as sodium bisulfite are often added to ophthalmic preparation to enhance the stability. These agents merely slow oxidation, however,

they can not prevent it altogether.

Many ophthalmic preparations discolor upon oxidation. This is especially true for phenylephrine, epinephrine, and physostigmine. Discolored products must be discarded. As a general rule ophthalmic preparations should be discarded within 1-2 weeks after they are first opened.

Measurement of the concentration on spectrophotometer : Before the drug is released, it must be ensured that the concentration of the drug is the same as labelled. To ensure this, one of the methods that we have standardised in our laboratory is the determination of absorption maxima which is characteristic of the particular drug. The principle that optical density is directly proportional to the concentration of the drug has been utilized. In our hands the method serves as an useful tool for internal quality control of ophthalmic solutions.





Absorption spectrum and calibration graph for Sulfacetamide, Homatrapine and Pilocarpine at different wave lengths on Spectrophotometer.

The concentration of active ingradient in the eye drops was measured spectrophotometrically. UV absorption spectrum of various preparations was plotted on a CE 580 recorder (Cecil spectrophotometer) to determine the absorption maxima of the individual drug. Then at peak absorption wave length a calibration graph giving straight line was plotted in absorbance Vs concentration. Standard graphs for pilocarpine, sulfacetamide and homatropine were thus prepared on their respective absorption maxima using normal saline with preservatives as blank. Pilocarpine showed peak at 218nm, sulfacetamide at 272 nm and homatropine at 215 nm. Pilocarpine and homatropine showed straight line relationship upto 10mg/100ml concentration while with sulfacetamide absorbance Vs concentration graph was linerar only upto 4mg/100ml.

To check the concentration of any one of these preparations, drops were diluted with the saline preservative base so as to get the absorbance within the limits. Concentration of the unknown drop prepared in the same base was calculated using the formula.

$$\frac{\text{Optical density of unknown}}{\text{Optical density of known}} \times \text{Conc. of known X Dilution factor}$$

The representative graphs showing absorption maxima and straight line relationship between concentration and absorption for pilocarpine, sulfacetamide and homatrophine are presented in respective figures. (Fig.)

Table:1

Following table shows the relationship between pH and osmolality of various ophthalmic preparations that are being manufactured at the Centre's Pharmacy.

Name of the Drugs	pH (± 2%)	Osmolality (±2%) (mOsm)
1. Normal Saline	6.40 - 6.65	290 - 310
2. Saline 5% eye drops	5.88 - 6.15	1495 -1555
3. Sulfacetamide Sodium 10%	7.12 - 7.40	975-995
4. Sulfacetamide Sodium 20%	7.22 - 7.50	1800-1875
5. Homatropine 2%	5.15 - 5.35	380-400
6. Pilocarpine nitrate 1%	4.01 - 4.17	320-340
7. Pilocarpine nitrate 2%	4.30 - 4.46	425-445
8. Indomethacin 1%	7.80 - 8.10	395-420
9. Eserine 0.25%	4.60 - 4.90	310-330
10. Corneal Preservative medium		
. a) M.K. Medium	7.20 - 7.40	280-300
. b) EP-II Medium	7.10 - 7.30	270-300
. c) RPC Medium	7.30 - 7.50	285-310

Manufacturing Of Eye Drops At Dr. R.P. Centre

Keeping in view the GMP, the following in built procedures

are followed for the manufacturing of eye drops at this centre.

Sterilization of glass-ware : The possibility of serious ocular infections resulting from the use of contaminated ophthalmic solutions has been amply documented in the literature. Such solutions have repeatedly been the cause of cornel ulcers and loss of eye sight. The following two methods are being used at this centre.

(A). By autoclaving - (Steam under pressure)

Sterilization by moist heat under pressure (121°C) is the method of choice for ophthalmic solutions unless the chemical nature of one or several of the ingredients of the solution forbids the use of heat. The total time required in the autoclave depends on several factors including the capacity of the heating element and the size and number of containers being sterilized, but usually it is 15 minutes to half an hour.

(B). By hot air oven

The other method used is by keeping the glassware in a hot airoven at 150°C for about 15 minutes. This kills all living organisms including spores and viruses.

Drugs and Preservatives of Pharmacoepial Grade : When limits are expressed numerically, the upper and lower limits of a range are all inclusive so that the range consists of the two values themselves and all intermediate values, but no value outside the limits.

The drugs and preservatives used in the manufacturing of ophthalmic preparations should be of Pharmacopoeial grade i.e. IP, BP, USP etc. They should confirm to prescribed limits of purity as recommended in the official monograph of the Pharmacopoeia.

Weigh accurately : All the ingredients are weighed accurately preferably using a electronic Metellar balance specially when lower concentrations are required. When the term drops is used in the Pharmacopoeia, the measurement is to be made by means of a tube which delivers 20 drops per gram of purified water at 15°.

Use of double distilled water : Distilled water used for eye drops is double distilled with the help of a fractionating column. The purpose of a fractionating column is to achieve an extensive liquid vapour interface so that equilibrium between ascending vapour and reflux can be rapidly attained. In the laboratory packed columns are being used, the packing may consist of single turn helicles(spirals) or wire or glass, glass-rigns etc. Distilled water thus prepared is again autoclaved before use.

Make the solution: Use a sterile conical flask or breaker and mix the ingredients thoroughly. Take proper care to avoid contamination at this stage. Stirrer used for mixing should be properly cleaned and autoclaved. Mixture should immediately be covered with a tin foil once it is ready. Now add suitable preservative and antioxidant, if required.

Sterilization of eye drop solution :

(A). Using micropore filters:

Micropore filters having diameter 47mm and size 0.2 µm, provide a favourable rating on each of the following requirements:

(i) Ease of use : extremely tough and require no special handling. These filters can withstand high temperature also.

(ii) Economical
(iii) Safe.

(B). Filtration procedure should be carried out under the Laminar Flow using UV light: The germicidal properties of ultraviolet light are used for sterilization. UV light kills all organisms including virus and fungi. The small scale preparation of eye drops by filtration are carried out in different syringes which can be used to sterilize small volumes of aqueous solutions.

Sterilization of eye drops containers : Permits the use of suitable plastic containers for eye drops. Plastic containers should be compatible with the preparations and should not release any undesirable materials. Containers are first washed with ordinary tap water, followed by rinsing in distilled water. Then they are dipped in distilled water containing an antimicrobial agent for a few hours. Vials are dried before use and kept in closed containers. For commercial use gamma radiation technique for plastic container is ideal.

Filling and labelling : Filling of the pre-sterilized vials is done either manually or by a automatic filling machine under laminar flow. Label of the drops should contain (i) the concentration of the active ingredient (ii) the name and concentration of the preservative used (iii) date of manufacturing of the drop.

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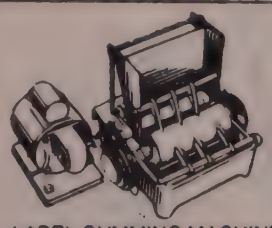

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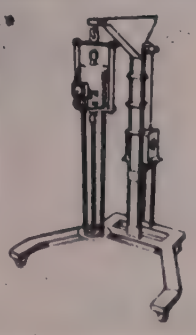

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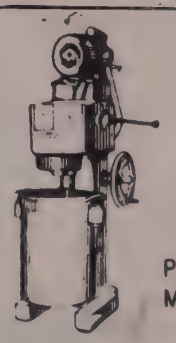

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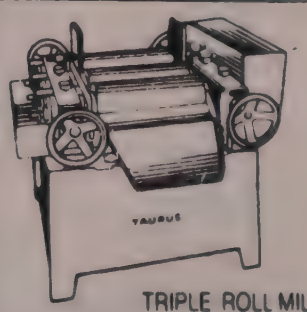

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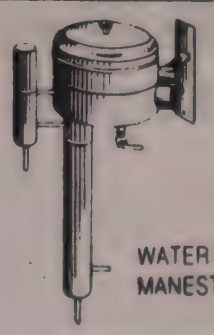

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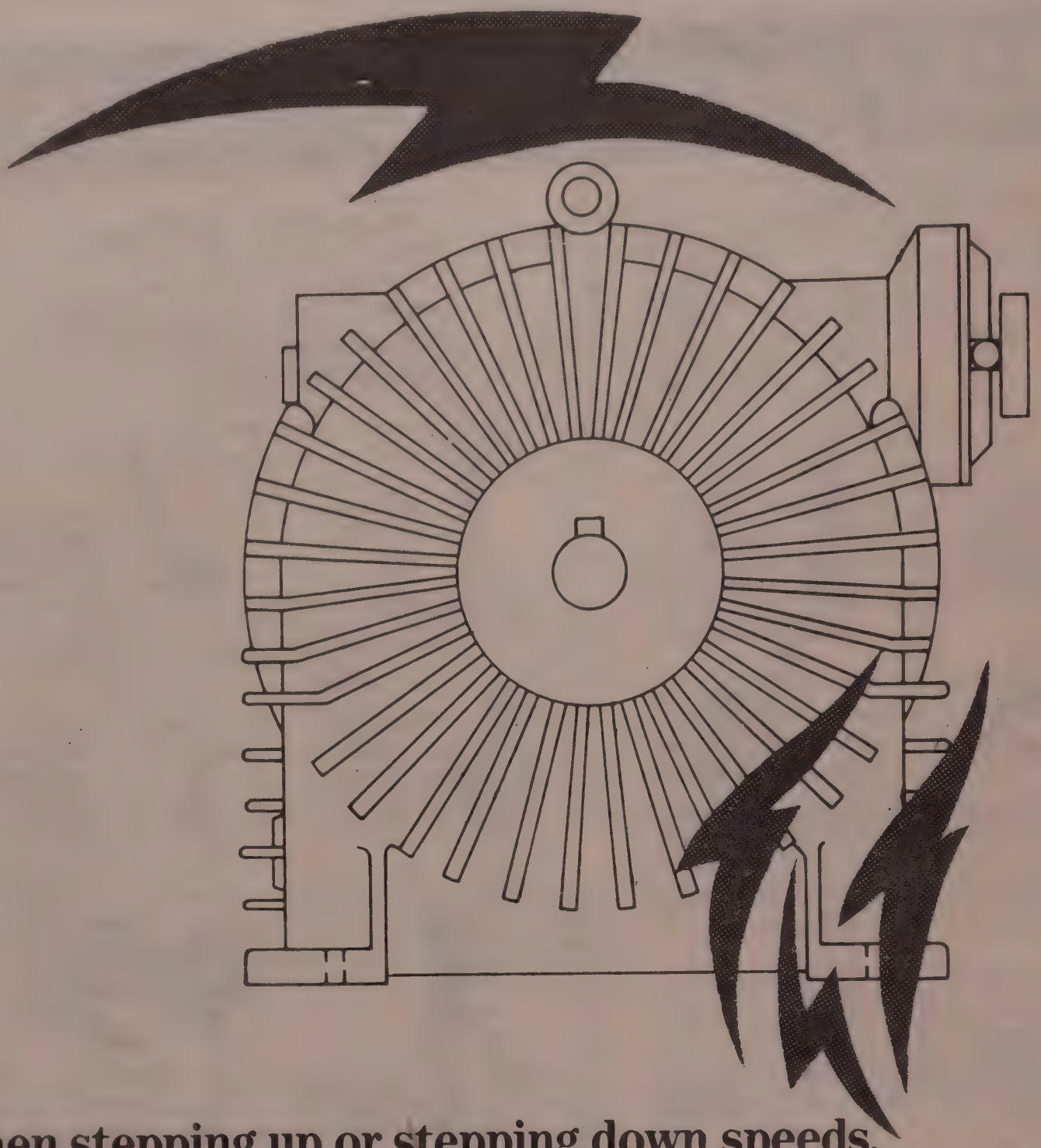

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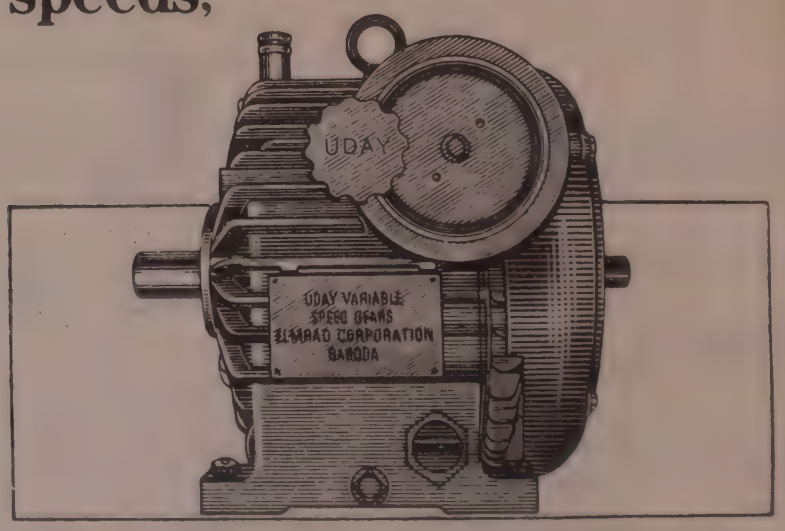

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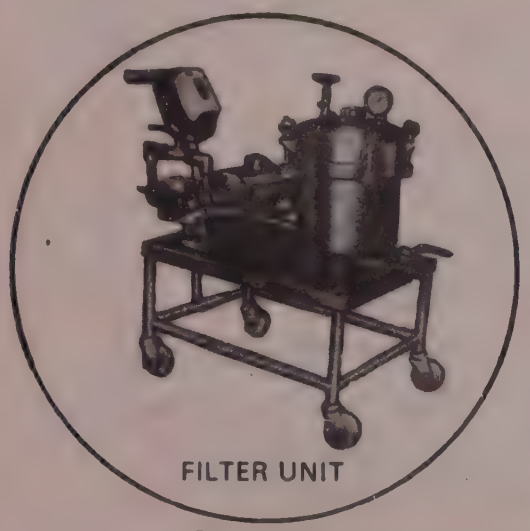

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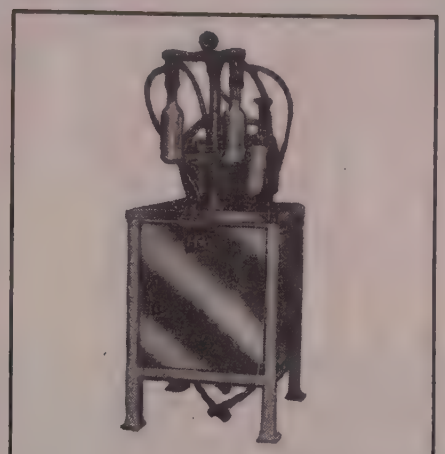

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RATIONAL USE OF DRUGS: WHAT DOES IT MEAN?

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Department of Pharmacology,
L.L.R.M. Medical College, Meerut - 250 004 (U.P.)

'Old is gold' an old saying, though applicable and true to many aspects of drugs, does not hold good for the changing pattern of modern drug usage. The empirical system of the use of drugs in the treatment of diseases is now considered outdated and is being gradually replaced by rational use of drugs which is certainly the hall mark of modern medicine. The older system of drug use though based on practical experience and one's own judgement, was undoubtedly empirical in the sense that, at that time, the knowledge of the pathological states and their biochemical derrangements was scanty and so was the case with the knowledge of the mechanism of action of these older drugs. The practice of scientifically controlled clinical trials and the statistical evaluation of the data obtained were totally lacking in earlier days.

In contrast to that 'empiricism' the scientific approach in modern medicine calls for rationalism in the treatment of disease states. The increasing health awareness in society, a plathora of investigative facilities available and better understanding of the pathological/biochemical derrangements resulting in more clinical awareness of the disease states and availability of extensive data on adverse drug reactions have all forced the treating clinician to be 'rational' in the use of drugs in patients. The economic gains to the drug industry resulting in the availability of an extremely large number of pharmaceutical products in the global market has heavily added to the present day irrational use of drugs. Amongst diseases if malignancy is a challenge for the entire medical science, drug abuse and irrational use of drugs are probably still more serious dangers for the surviving humanity. In view of its extreme importance rational use of drugs is now considered a global priority (Editorial, 1988).

What Is Rational Use Of Drugs ?
'Rational use of drugs' could be defined as the use of drug(s) by the patients which is (1) essentially required for the treatment of his/her disease, (2) extremely safe, (3) least hazardous, (4) cheap and (5) based on sound judgement and scientific reasoning in the light of the present day knowledge of the disease states. No doubt, this 'rationality' is likely to be 'relative' depending on many factors but it must be the best possible in the prevailing circumstances. Rationality in the use of drugs, infact, is not the sole concern of only the prescribing community. The manufacturer, the prescriber, the dispensing pharmacist, and the consumer all are responsible, but of course in varying degrees, for rational use of drugs in the society.

Levels Of 'Rationality' : In the clinical usage of drugs there could be different levels of rationality. These levels can be better appreciated if the prescriber, the dispenser and the consumer give due consideration to a number of questions e.g.:

(1) Is the drug essentially required to be consumed by the patient?
(2) Amongst the drugs available for the treatment of that disease, is that particular drug 'the best' in terms of efficacy, safety, dependability and economics?
(3) What are the possible gains and hazards to the patient if he/she uses that drug?
(4) Do the 'gains' overweigh the possible 'hazards'?

Keeping these queries in mind one

could think of rationality at the level of manufacturers, distributers, prescribers dispensers and also, perhaps more important, at the level of consumers as well.

Factors Responsible For Irrational Use Of Drugs : A variety of factors involving manufacturers, prescribers, distributers/suppliers, dispensers and the consumers are responsible for the present day irrational use of drugs in the society. A detailed consideration of these factors as given below is essential before measures to combat this problem of irrationale use of drugs in the society can be appreciated and spelled out.

(A) MANUFACTURERS :

(1) Rampant Availability Of 'too Many' Drugs In The Market : The monetary gains to the pharmaceutical industry along with the support of the prescribing community have resulted in an unchecked proliferation of innumerable drug formulations in the market (Jaju, 1985 a & b). The trend has been to put up a new formulation and push up in the market with extensive pressurised marketing publicity. The larger pharmaceutical houses capture the market taking advantage of their reputation. On the other hand smaller pharmaceutical concerns flood the local market with their "Substitutes" at competitive rates. In these situations over the counter (O.T.C.) sale of drugs (Jaju and Saxena, 1986; Nayyar and Mehra, 1985) enormously increases the irrational use of drugs.

(2) Shortage Of Essential Drugs In The Marker : The shortage of 'essential drugs' in the market contributes in a big way to the irrational use of drugs. The selection of essential drugs is a dynamic process and must be continued unabated (W.H.O. 1977, 1979, 1983, 1985, 1988). The list of these essential drugs (Jaju and Saxena, 1987) for a particular population may vary depending on many factors particularly the morbidity pattern, yet their availability for the public must be ensured by the administrative machinery. This can be achieved by increasing their production and modulating favourably their distribution system according to the needs (Jaju, 1986; Jaju and Katiyar, 1985). However this will require extreme cooperation of the manufacturers, distributers, and also of the prescribers.

(3) Irrationality In Nomenclature Of Drugs : The rampant nomenclature of their branded drugs by the pharmaceutical houses has resulted in a situation where exactly similar names of similarly phonating names with trivial differences in their spellings contain pharmacologically active but different ingredients (Agarwal, 1987: Jaju and Kumar, 1988) resulting in enormous possibilities of alternative prescribing /dispensing of drugs. In order to check such possibilities it is imperative that there should be some check on nomenclature of newer formulations. However, it is gratifying to note that atleast some pharmaceutical houses have accepted pharmacological names as their trade names in cases of a number of drugs (Jaju and Kumar, 1988).

(4)Availability Of 'Magic Bullets' And Unnecessary Formulations In The Market : Often the manufacturers publicise the discovery and development of new drug formulations as magic bullets' which in their opinion, are far superior than the existing ones. Such 'magic bullets' because of the high toned claims of the manufacturers, do get a local market but only for short periods.

These 'magic bullets' be put to rigorous clinical trials under controlled conditions and the data be subjected to statistical evaluation before the publicity of these 'magic bullets' is allowed. Unnecessary drug formulations particularly fixed dose combinations should be gradually weeded out from the market (Bindal et al., 1983).

(5) 'Marketing Pressure' Of Pharmaceutical Houses: Pharmaceutical houses just to popularise their products, resort to a variety of marketing pressures. These include gifts to the prescribing community and whole sale dealers, 'Silver-lined' claims of their products and fantastic publicity in newspapers and by audiovisual propoganda. No doubt publicity is desirable and must be allowed, but it is 'pressurised publicity' which is undesirable and should be checked.

(B) PRESCRIBERS:

(1) Rampant Practice Of 'polypharmacy' By The Prescriber : No doubt polypharmacy has its own therapeutic advantages, but its rampant practice is a 'professional stigma'. The prescribing community, faced with numerous problems like inadequate investigative facilities, health education, malnutrition, and the changing pattern of clinical presentations etc most of the time resorts to 'polypharmacy'. Certainly this poses terrific burden on the economically weaker section of the society. It is unfortunate that chemotherapeutic agents, tonics and vitamins alone take away more than 50% of our drug expenditure (Jaju, 1985 c). In view of the poor economic conditions, particularly in the developing countries prescribing community should be reasonably conservative in prescribing chemotherapeutic agents particularly antibiotics (Jaju, 1986 and Jaju et al., 1986). Vitamins and tonics should not be prescribed just to make the prescription"Comprehensive".

(2) Inadequacy And High Cost Of Investigative Facilities : Even though there has been tremendous expension of medical investigative facilities now available for the population, yet the facilities for investigations are inadequate. Even simple and cheap investigations can not be routinely carried out in all patients. Sophisticated investigative facilities requiring advanced technologies are available only for the effluent and highly placed members of the society. As such the prescribing community resorts to poly pharmacy and prefers to use drugs with wider antimicrobial spectrum. On the other hand, it is also pertinent that the prescribing community should try to curtail, as far as possible, the demand for such investigative facilities. Such curtailment is possible only with the utilization of professional skills to the best.

(3) Inadequate Training In Pharmacology For 'Rational Use' Of Drugs: The time bound and examination oriented training in pharmacology in the medical curriculum is largely a cram-

ming exercise (Jaju, 1987). During the training period neither the students nor the teachers are much concerned about the practical relevance of the type of training required at least in terms of rational use of drugs. Perhaps it is high time that rationality in the use of drugs is given due consideration in the curriculum of pharmacology during medical training.

(4) Lack Of Continuing Medical Education/refresher Courses In Pharmacology : Even though almost every medical doctor after medical graduation is involved in the treatment of patients with drugs, but hardly a handful of these are ever privileged for refresher courses and continuing medical education in the field of pharmacology. It is surprising that even in medical teaching hospitals drug prescriptions have been the subject of criticism (Kapoor et al., 1985; Jaju, 1985 b). After graduation the doctors get the "drug product information" only through medical representatives who provide to these doctors ' their self-processed' information and that to for only about a handful of their branded products. In fact, majority of the members of the medical community, in the years to come, almost starve academically because of non-availability of authoritative scientific literature on these products. Concised yet comprehensive, authentic and readily available literature on individual drugs (Jaju, 1988) and drug formulations (Jaju, 1989) can go a long way to meet such needs of the prescribing community.

(C) PHARMACIST

(1) Unchecked Dispensing And Substitution Of Prescribed Drugs : Unchecked over-the-counter (O.T.C.) sale of drugs (Nayyar and Mehra, 1985; Jaju and Saxena, 1986; Hede et al., 1987) in the market and inadequacy of qualified pharmacists in the country have been contributing to a large extent not only to unchecked dispensing of drugs but also to the dispensing of 'substitutes' by the pharmacists/chemists. Many a time, the selection of these 'substitutes' is based on availability at the counter and economic gains to the seller rather than any ethics of dispensing. It appears imperative to restrict the sale of O.T.C. drugs only to those drugs which are therapeutically effective, reasonably safe and their use may not require strict medical supervision (Jaju and Saxena, 1986).

(D) CONSUMER :

(1) Self-medication And Storage Of Left-over Drugs By The Patients : Self medication of drugs by the consumers is wide spread in the society (Agarwal and Gupta, 1982). Several factors including previous experience of the consumer and his fellow friends/neighbourers/colleagues, mass publicity of drugs, O.T.C. sale of drugs and economic reasons have forced the consumer to practise the habit of self-medication and storage of left-over drugs. No doubt self medication of O.T.C. drugs, which are reasonably safe is justified but storage of left-over drugs for future use, availability of substandard drugs in abundance and use of all types of drugs without medical supervision/guidance are totally unacceptable in rational use of drugs and must be discouraged.

(2) Consumption Of Drugs On Prescriptions Of Other Patients : In order to cut short the medical expenses the patients often consume drugs prescribed for other patients on the basis of similarities in their symptoms and history of the disease. They often take the same drugs which had been prescribed by a doctor to another patient with similar symptoms. Such a practice should be largely discouraged in the society.

(3) Craving For Injectables, Costly Drugs And Specialists By The Patients : There is a general feeling that injectables and costly drugs are superior than orally administered and/or cheaper drugs. This may be true in certain circumstances but not in every situation. Doctor's advice in regard to such a misconception can go a long way in curbing patient's attitude towards injectables and costly drugs.

There is also a feeling that it is better to contact a specialist for ailments. No doubt specialists have their paramount importance and crucial role to play in the management of critically ill and chronic patients, yet the craving for specialists particularly by the rich class even for minor ailments is on the increase. These specialists though provide a positive psychological impact beneficial for the patient, yet their involvement should be need based.

SUGGESTED MEASURES FOR CURBING IRRATIONALE USE OF DRUGS :

In the light of foregoing discussion and facts the following measures are suggested for curbing irrational use of drugs prevalent in the society.

1. Proper/adequate training of medical students in pharmacology for rational use of drugs.
2. Total ban on irrational/unnecessary drug formulations in the market.
3. Adequate production and ample supply of 'Essential drugs' for the masses particularly in times of need.
4. Adequate investigative facilities at affordable cost.
5. Effective role of pharmacists as an essential link between the prescriber and the consumer of drugs.
6. Drastic curb on O.T.C. sale of drugs.
7. Public education to curb self-medication and storage of 'left-over' drugs.
8. Postmarketing survillience studies/therapeutic auditing and feed back of the date to the prescribing community/administrators/manufacturers and Drug regulating authorities.

Even though "Health for all by 2000 A.D." is viewed as governments responsibility, it cannot be realized without whole hearted commitment from everyone contributing to the vast infrastructure of health care delivery (Mahler, 1988).

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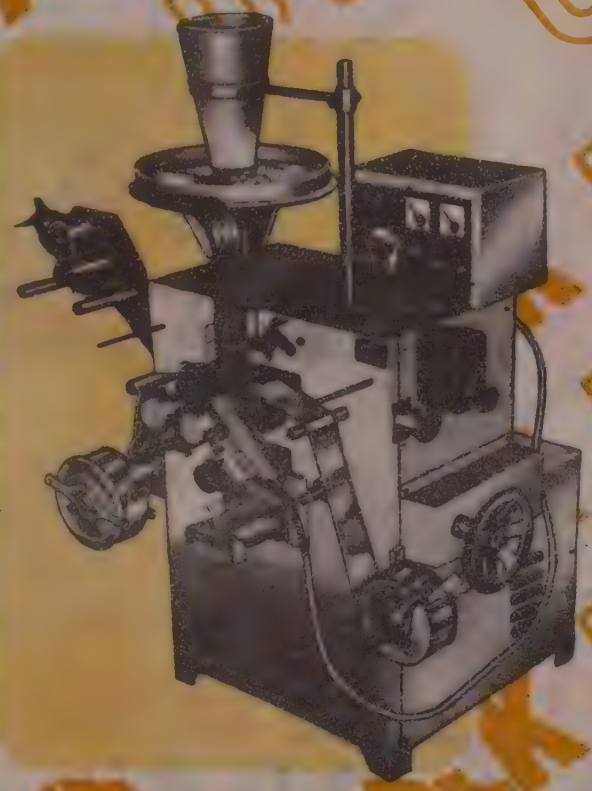

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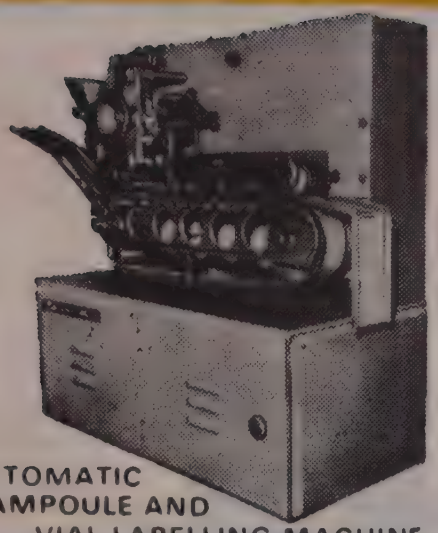

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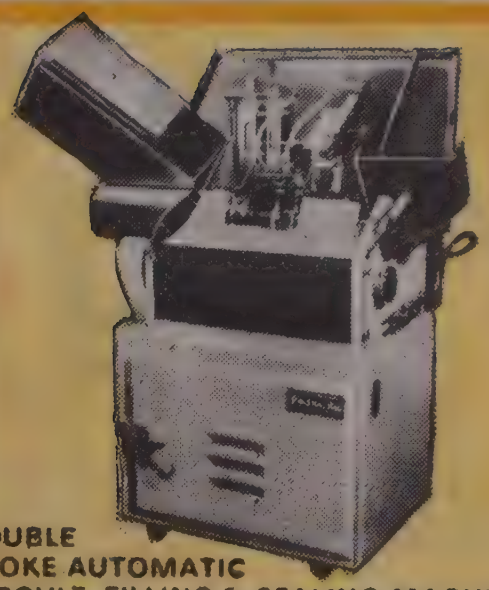

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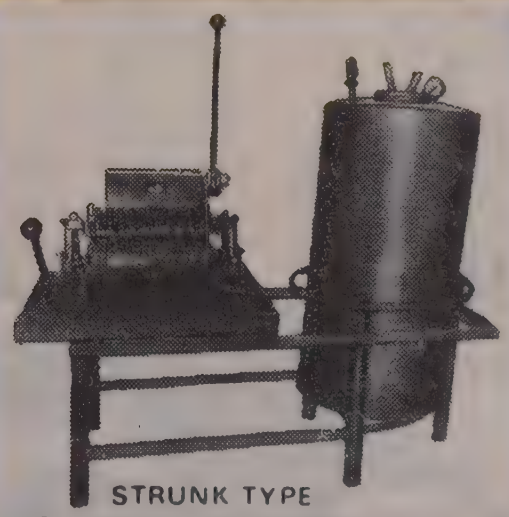

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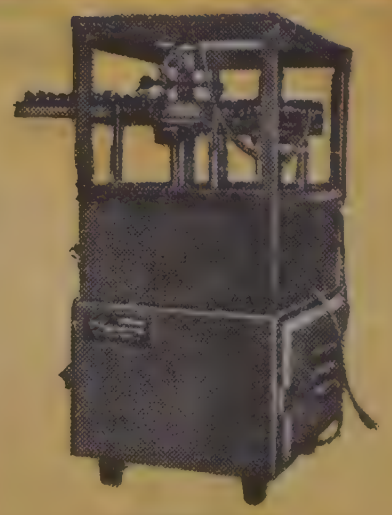

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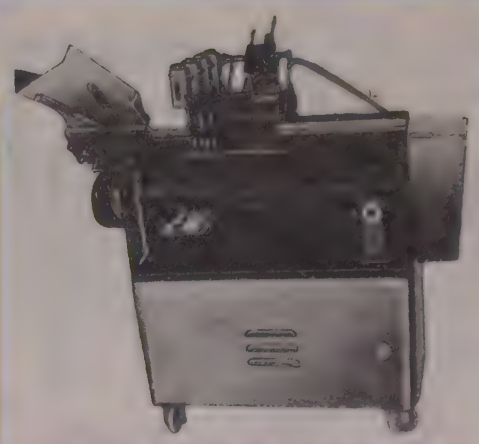

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STABILITY INDICATING TEST PROCEDURE - IN PERSPECTIVE

Dr. V. Kumar & Mr. Sunder N.
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A stability indicating test procedure is a method which differentiates and quantifies the active ingredient being assayed from the other active ingredients, excipients, synthetic impurities and degradation products present in the dosage form. Apart from its specificity, it should also be sensitive, reproducible and accurate [1].

The need for developing Stability Indicating Test Procedures has become more essential today as many assay methods described in the official compendial drug monographs are not stability indicating. The importance of stability indicating test procedures has been underlined by the U.S. F.D.A. which requires product expiration dates to be based on stability data, using stability indicating assay procedures[1]. Various factors contribute to the non-specificity of an assay procedure. Firstly, if the dosage form contains two or more active ingredients, then these actives may interfere in the assay of the particular active ingredient. Interference may also occur due to the excipients used viz. preservatives, diluents, chelating agents, antioxidants, etc. Secondly, the raw material used may introduce impurities in the form of its starting materials and its impurities, intermediates or by-products. Product nonspecific impurities can also get introduced during its processing and manufacture. Finally, the degradation/decomposition products of the active ingredient contribute greatly to the nonspecificity of the assay method. These degradation products may arise due to drug-drug interaction between two or more actives, drug-excipient interaction, drug dosage form-container/closure interactions such as leaching, permeation, etc. and the decomposition of the active ingredient itself due to hydrolysis, oxidation - reduction, photolysis, racemization, etc.

Stability indicating assay procedures are essential for new drug molecules as it may contain unknown degradation products, known/unknown impurities from raw materials, structually related reaction by-products/compounds and intermediates. In case of New Dosage Forms, the active ingredient may be unstable in the developed formulation due to its incompatibility with the other actives or inactives used, and hence a specific assay method is required. Similarly, a new product formulated using a new excipient has to be studied for its compatibility by a suitable specific test procedure. In formulations of New Drug Delivery Systems such as Sustained Release Dosage Forms and Target Drug Delivery Systems, it becomes imperative to develop a sensitive and selective assay method to ensure the amount of intact drug moiety made available.

The stability indicating assay procedure may be either a conventional or an instrumental method. Conventional methods have advantage of low cost and simplicity while instrumental methods require lesser analysis time and possess greater accuracy for small amounts of sample. Some of the methods are discussed below :

1) Titrimetry :

It is one of the earliest methods used for the assay of drug substances. Nonaqueous titration is frequently used for the assay of amines, alkaloids, sulphonamides, antihistamines and amino acids in pharmaceutical preparation. Oxidation - reduction titrations can be used for determining the amount of Ferric Iron and Total Iron present in pharmaceutical preparations such as Iron Tablets and Capsules used for treatment of anaemia related disorders [2].

The iodometric assays of β-Lactam antibiotics such as Ampicillin and Benzylpenicillin Potassium (Penicillin G) are used for the stability determination of their respective pharmaceutical preparations[3]

2) Ultrviolet/visible Spectrophotometry :

The low degree of specificity of Ultraviolet and Visible Spectra makes it essential to first determine, by use of T.L.C. etc, that the absorption is due to the active only. Interferences due to excipients must be eliminated. If presence of any degradation product is indicated in T.L.C., then it must be isolated and scanned to verify the absence of any significant absorbance at the wavelength of maximum absorbance of the active ingredient. Spectral selectivity can be enhanced by use of Difference Spectrophotometry, Derivative Spectrophotometry and Dual Wave length Spectrophotometry. When spectra of two or more well defined components overlap, then Vierordt Multiwavelength Technique, Second or Higher Derivative Spectrophotometry, etc. can be used to measure individual concentration.[4]

For Example, Second Derivative Spectrophotometry has been used for assay of mixtures of Dicloxacillin Sodium and Ampicillin Sodium, which are semisynthetic penicillins with closely overlapping absorption spectra, in pharmaceutical preparations such as injections and capsules.[5] Also mixtures of Cephalosporins such as Cephaloridine and Cephalothin Sodium can be assayed by this method. Vierordt Multiwavelength Technique is used for Limit test of Amphotericin A in the antifungal antibiotic Amphotericin, which consists mainly of Amphotericin B[4].

3) Colorimetry :

When a drug has little or no useful absorption in the U.V./Visible region, then it is subjected to a chromogenic reaction to form a highly absorptive chromophore. Colorimetry is made specific by use of colour reagent which is selective for the drug molecule only and not for degradation products, impurities and other formulation excipients. The reaction time, pH, solvent temperature, reagent excess and other factors, required to obtain stable chromophore, must be optimised for better selectivity and sensitivity. Examples are tetrazolium assay for corticosteriods, diazotisation and coupling with N-(1-Naphthyl) ethylenediamine, etc.[4] Isoniazid, is officially analysed by B.P. (1980) bromimetrically. Studies indicate possibility of non specificity of method as any degradation product, susceptible to oxidation, may interfere. Hence, use of 6,7-dichloroquinoline-5,8-dione as chromogenic reagent to react with intact hydrazide moiety giving green coloured condensation product is recommended. The method is specific, sensitive and fast and hence stability indicating[6].

4) Thin Layer Chromatography :

It is one of the most widely used techniques for separation and identification of drugs, either in pure state or in formulations. Due to its low cost, simplicity and high sensitivity, it can be used by small scale drug manufacturers as an alternative means, to differentiate between the active drug and its degradation products/related compounds. The mobile phase moves across a uniform thin layer of stationary phase (e.g. Silica Gel, Alumina etc.) bonded to a plate of Aluminium foil, glass or plastic. The separation occurs due to different rates of migration which depends on differences in solubilities in mobile phase and degree of adsorption on stationary phase. It is denoted by its Retention factor (Rf Value). After development, mobile phase is evaporated and spots located either by visual colour, UV light, fluorescence quenching, iodine vapour, spraying with chromogenic reagent etc. Degradation products are detected by running a standard simultaneously. If drug and its related substance have same Rf value and overlapping of spots occur, then two dimensional T.L.C. can be carried out by chromatographing the chromatographed plates by turning it at right angles and using a different mobile phase.

Quantitative T.L.C. is performed by spotting known amounts of both sample solution and standard solution along with an appropriate blank on a plate. This plate is then developed using a suitable mobile phase. After the solvent front reaches the desired height, the plate is removed, the mobile phase allowed to evaporate, and then dried. Quantitation is done by :

(1) Comparing intensity or size of spots on plate by insitu methods like photodensitometry or fluorescence measurement.
(2) The spot is marked and scraped into a vessel, eluted with suitable solvent, concentrated and absorbance measured in U.V. or Visible region or subjected to chromogenic reaction to yield coloured/ fluorescent derivative.

Advantage of T.L.C. over H.P.L.C. is low cost, ease of use, a large number of samples can be run simultaneously, greater flexibility of choice of mobile phase and permanent location of separated spots. Use of high speed automated T.L.C. scanners has improved quantitation speed and sensitivity.

Certain cephalosporins can be determined by T.L.C. by developing in an acidic mobile phase, spraying with Fluorescamine and quantitated insitu by measuring fluorescence emission or by using a silica plate impregnated with fluorescent indicator and measuring fluoreseence emission directly. The high sensitivity, specificity and accuracy makes the method stability indicating[7,16].

5) High Performance Thin Layer Chromatography (H.P.T.L.C.) :

H.P.T.L.C. is T.L.C. improved by use of new stationary phases, chromatographic development modes, automated sample application devices and use of microprocessor controlled densitometer. Here, plates have much smaller particle size (2-7 μm) and narrow particle size distribution. This makes it

faster, more reproducible, sensitive, accurate, precise and having greater degree of resolution than T.L.C[4].

It is used to separate complex mixtures for both qualitative and quantitative analysis. The developed plates are usually visualised, recorded by photography or quantitatively analysed using a scanning densitometer, or lately by use of video camera and an image processing system. Advantage is many number of samples can be run simultaneously while disadvantage is inability to use another identification technique after elution as volume of sample is very low[8].

For Example; in the analysis of Oxyphenbutazone, ordinary T.L.C. separation and quantification cannot be done due to poor resolution. Hence, to separate and quantify Oxyphenbutazone and its six potential decomposition products, H.P.T.L.C. is carried out. On-plate oxidation is avoided by use of antioxidants and plates treated with chelating agents to chelate metal ions present in them which act as oxidation catalysts. Quantification is done by reflectometric determination of each spot using chromatogram spectrophotometer. Due to greater levels of detection, determination, resolution and specificity, method can be used as stability indicating assay for raw materials and commercial formulations[9].

6) Gas Chromatography :

It is used for determination of volatile and thermally stable substances. Here, the separation of components of a sample occur by partitioning between the stationary phase (may be either solid or liquid coated on solid support) of a column maintained at a definite temperature and a mobile phase (carrier gas) flowing at a constant rate. On injection, the samples are volatilised by a pre-heated oven, passed through the column and after separation based on their retention times, are detected by detectors such as FID, TCD, etc.

Advantage of G.C. is high sensitivity. High selectivity can be achieved by adjustment of carrier gas flow rate, column temperature, type of column, etc. Main disadvantage of G.C. is possibility of a change in molecular structure as it passes through the chromatographic system, due to thermal stress. Drugs having high molecular weights, poor volatility, relatively polar substituent groups (which interact with stationary phase) and possessing thermal instability are derivatised by silylation, acetylation or methylation to give thermally stable and volatile derivatives. Temperature programming is done for complex mixtures wherein, more volatile components are eluted at low column oven temperatures and then column temperature is raised to volatilise less volatile components.

GLC can be used as a tool to detect and determine quantitatively the amount of residual solvent or solvent of crystallisation present in a drug e.g. presence of methanol in Streptomycin Sulphate[3].

Similarly, it is used to detect and quantify the amount of two known impurities of Ampicillin Sodium viz. Dimethylaniline and Dichloromethane. Also, it provides a sensitive method for separating and distinguishing between closely related compounds as, for example, the cis and trans-isomers of Tranylcypromine Sulphate, in which it is used to limit the unwanted cis-isomers and cinnamylamine[3].

7) High Pressure Liquid Chromatography (H.P.L.C.) :

H.P.L.C. is one of the most popular analytical techniques today. The separation in H.P.L.C. is done by partitioning between a mobile phase (solvent system) and a stationary column material and depends mainly on the solubilities of the solutes. Mobile phase is pumped at a high pressure through a column packed with fine particles of silica or chemically modified silica, etc. The sample is injected and the solutes after separation, enter the detector (viz. U.V., Fluorescence, Refractive Index etc), the data from which can be quantified. As compared to G.C., non volatile, thermally unstable or polar/ionic compounds can be analysed. H.P.L.C. has gained importance in Stability Studies due to its high resolution capacity, sensitivity and specificity. Unlike G.C., as technique is nondestructive, eluted compounds can be collected for further analysis. The high cost of equipment is a limiting factor in its widespread use.

Special techniques used are :

(1) Gradient Elution - Used for compounds with wide differences in retention time, wherein elution strength of eluate is increased during a run by changing polarity, pH or ionic strength.
(2) Derivative Formation - to enhance sensitivity and selectivity by forming U.V. absorbing or Fluorescent derivatives[4].

H.P.L.C. can be used to resolve and determine the active drug and small amounts of its degradation products, wherein the existing official methods prove inadequate and nonspecific e.g. Dextrose, used in pharmaceutical preparations, to adjust osmolarity of solution, degrades during autoclaving or on storage to give 5-Hydroxymethylfurfuraldehyde. Official methods include a simple UV Spectrophotometric limit test, which may be non specific at the wavelength mentioned due to presence of other substances having absorption at the same wavelength. Here, H.P.L.C. can give the desired selectivity[11]. Similarly, Chlorpromazine is analysed officially either by U.V. absorption which may be nonspecific or by differential absorption which is time consuming. H.P.L.C. provides a means to differentiate between Chlorpromazine and its degradation products, Chlorpromazine Sulphoxide (which may possess phototoxic side effects) and Chlorpromazine Sulphone. Method becomes stability indicating due to its specificity and sensitivity[12].

In case of a group of compounds such as Benzodiazepines which are structurally related, H.P.L.C. is the method of choice. Thus, benzodiazepines such as chlordiazepoxide,

diazepam and their pharmacologically active metabolites can be analysed simultaneously and are particularly useful for clinical analysis.

Minute amounts of impurities which may be introduced from container, closures etc. can also be detected and determined. E.g. the case of Boehringer Ingelheim's New Drug Application for *Atrovent* MDI (metered dose inhaler), a therapeutic bronchodilater. The FDA (U.S.A.) expressed concern over the presence of an unidentified peak eluting at 4.2 minutes present in the liquid chromatogram of the active drug ingredient, Ipratropium Bromide, in the drug product *Atrovent* MDI. The Pharmaceutical Company was asked to identify and quantify the product and to determine its toxicology. The two known possible degradation products, Tropic Acid and Apo-Atrovent were chromatographed and neither eluted at 4.2. minutes thereby eliminating possibility of any relation of the unknown compound to active drug or its degradation products. A Atrovent MDI placebo gave a peak at 4.2 minutes. Extractions of MDI container placebo indicated seals of diaphragm, metering tank and O-ring as possible sources.

Individual chromatograms proved diaphragm seals to be the cause. The substance was isolated and analysed by UV,IR,NMR,MS etc. and found to be N,N^1-di-o-tolyl-guanidine, a component used in rubber processing[13].

One of the major problems encountered in H.P.L.C. analysis is the peak purity, which is expressed as absence of coeluting components e.g. In separation of two isomers, theophylline and paraxanthine by H.P.L.C., there is invariably interference of paraxanthine in analysis of theophylline, due to coelution and detection at the wavelength of interest. Hence, it becomes essential to ascertain purity of the peak before the method can be validated[14].

An important aspect of any method development is the proper validation of the analytical method employed. Validation should be done with respect to the selectivity for the desired substance, limits of quantitation, limits of detection, accuracy and reproducibility. In case of chromatographic systems, stabilities in solution and within the chromatographic system must be studied and validated and only then the developed method can be said to be a stability indicating analytical procedure.

In summary, Chromatographic Methods particularly H.P.L.C. is a trend at this time and many analysts believe H.P.L.C. as the only method of choice for developing stability indicating test procedures. However, it is essential to select the most sensitive, most accurate and most specific method out of the whole field of analytical procedures for any particular problem. From this view point, different analytical procedures have been discussed to show that for instance, Spectrophotometric methods/Colorimetric Methods or Simple Titrations should also be considered besides Modern Instrumental Methods.

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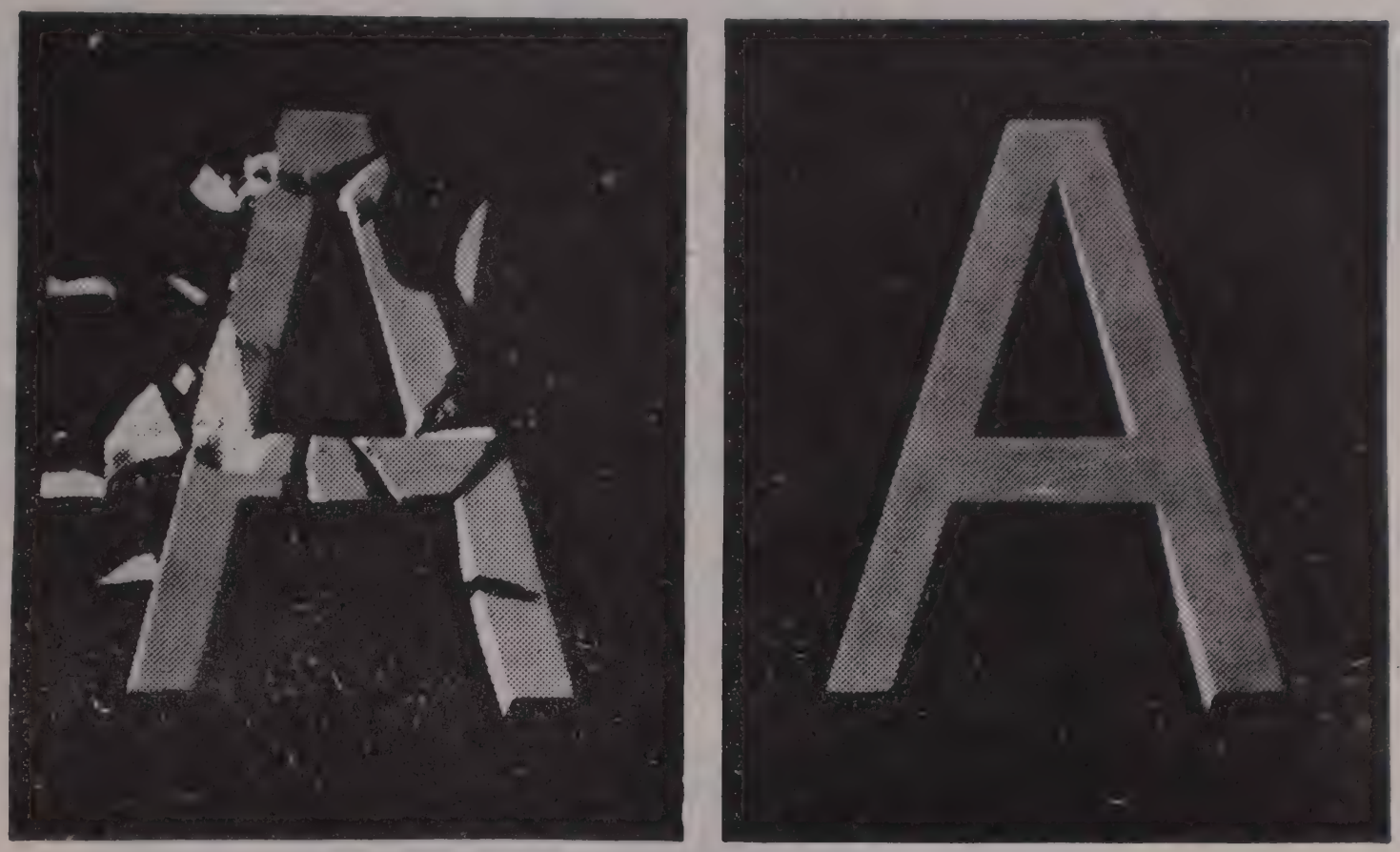

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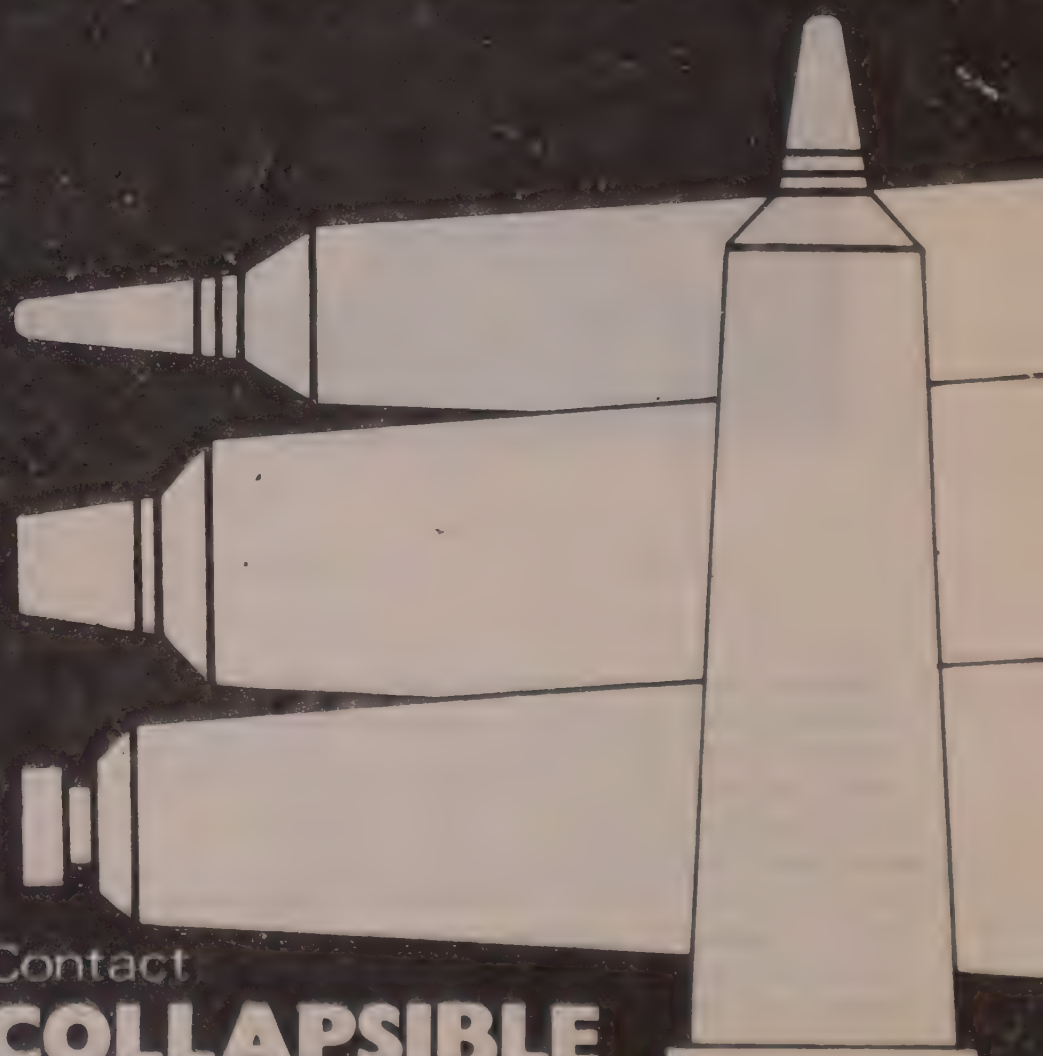

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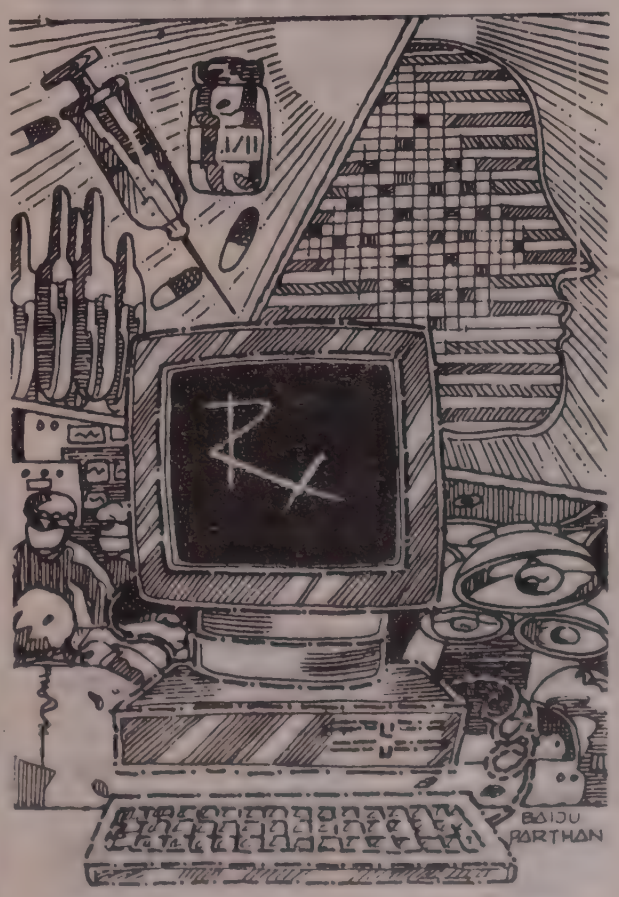
Computers hold tremendous promise for enhancing the work of pharmaceutical professionals. Their capacity to store large amounts of data on drugs and patients and give instant online access to it, display a great potential to improve patient service and promote business objectives. With the advent of microchip and powerful but compact microcomputers, computerised systems are within the reach of the smaller institutions also.

Today computers are used in all walks of life-from a microwave oven in the Kitchen helping the modern housewife, to automated control of satellites probing distant planets. A decade ago computer appeared like a luxury, and were avoided by many a profession, only to be invaded by them gradually - their use becoming an indispensable part of the same professions. The profession of pharmacy is no exception to the invasion of the computers. Their use has made tremendous impact on the growth and advancement of profession.

Until recently mostly large hospitals, pharmacies and pharmaceutical companies could afford the high cost of implementing computerised pharmacy systems. They could use them in many facets of the profession like manufacturing, drugs information, analysis and research, management of a stocks and drug distribution, dispensing, maintenance of accounting etc. For the smaller institutions the prohibitive factors included the high cost of the computer hardware and a lack of available software programs designed to meet their specific and unique needs. Today, with the advent of the microchip, powerful but compact microcomputers/personal computers are available at affordable prices. Several companies are offering computer programs that can run on these small computers providing a number of attractive facilities to the working pharmacist and those managing pharmaceutical facilities



AREAS WHERE COMPUTERS CAN HELP :

Following is a general description of the facilities that can be expected from a computerised system.

Drug Information :

With the availability of large disk storage even on small computers, it is

now possible to store large amounts of useful drugs information. In addition to large storage capacity, disks also offer a great advantage by providing instant access to any part of the stored data.

The drugs can be classified in accordance with an agreed therapeutical classification and useful information can be entered for each of the drugs of a particular class.

Following is a suggested structure of data stored for each drug:

* Indications
* Contra-indications
* Mode of action
* Mode of administration
* Side effects
* Precautions
* Dosage

In addition to the above data generic names, trade names, supplier names and keywords to denote various attributes of the drugs can be entered and links established between them. With the availability of appropriate facilities, the computer system will be able to maintain several indexes automatically as data is being entered or changed. With the help of these indexes, a computer user can display a list of drugs satisfying a set of conditions by typing the keywards an enquiry parameters.

Computer programs can give rapid recall of drug information through several routes. For example,

- by typing the therapeutic class to produce a list and selecting the required drug.

- by typing the first few characters of the generic name or trade.

- by typing a predetermined code number.

Drug interaction table is another useful drug information where computers can be of invaluable help.

Drug Dispensing :

Computer programs will be able to cater for inpatient prescription management as well as outpatient prescription control. They can produce clear professional looking labels with minimum amount of data entry, caution the pharmacist on interactions and overdoses, update drug inventory and produce reports.

Given below is a more detailed list of what can be expected in a dispensing program :

– Quick selection by typing the first few characters of the drug name or a code.
– Multiple dosage instructions retrieved by simple codes.
– Verification of input as data being typed.
– Cautionary messages conforming to official recommendations tagged to each drug will be automatically printed on labels.
– Interction warning facility to alert the pharmacist.
– Special warning messages tagged to warn pharmacist eg., black listed drugs.
– Display of label on the screen before printing if required.
– Facility to alter the wording or add additional mesages at the discretion of the pharmacist.
– Repeat labels printed on request.

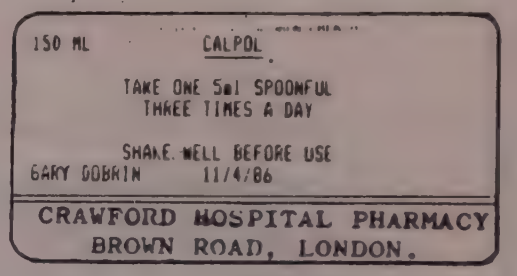
– Recall of previous label or recall of patient name on previous label for subsequent items.

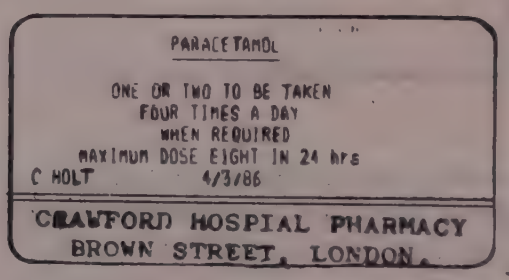
– Bi-lingual labels: Pre-recorded dosage instructions and label wordings to allow even those not knowing a language to print bilingual labels.
– Pricing of prescriptions.
– Automatic building up of orders while dispensing for supplies from wholesaler.
– Automatic inventory update.
– Online enquiry of patient's drug history.
– Recall of patient names to whom special drugs are issued-eg. narcotics.
– Printing of daily lists of drugs dispensed.

The facilities in the labelling program will make it easier to produce quality labels by an experienced as well as an inexperienced pharmacist.Blank label supplies can be obtained in the market in continuous stationery form with a logo/address if desired.

In large installations like hospitals, the dispensed drugs can be stored and linked to the patients medical history file. Such information can also be of immense help in tracking the patients to whom a particular batch of drug was issued.

A sample label produced by a computer is shown below.





Drug Inventory :

Programs can be used to establish and maintain inventory details and print required reports. The expected facilities are :

– Stock take on:

For recording initial quantity in stock.
– Stock receipts:
For recording bulk receipts.
– Stock issues.
– Inventory maintenance:
For entry, enquiry, amendment and deletion of stock information like -
– Issue unit
– Unit cost.
– Minimum stock level..

– Maximum stock level.
– Recorder level.
– Supplier details.
– Shelf life.
– Stock on hand.
– Information on batches.

– Reports:

– Stock on hand reports by generic names, brand names.

– Recorder reports.

– Audit reports.

– Warning reports based on expiry date of batches.

– Maintenance of stocks at different location.

Miscellaneous Areas of Use:

There are other areas relating to pharmacy where computer programs can be used:

1. For maintaining formulary information and manufacturing instructions.
2. For maintaining information on treatment for poisoning and overdose.
3. For maintaining small stock of essential drugs at inpatient wards.

KNOW YOUR REQUIREMENTS .

There are many ready-made computer programs available now providing different facilities to the pharmacist. It is impossible to find one singe vendor providing all imaginable features to satisfy every kind of pharmacist. It will be necessary to make compromises while selecting ready-made packages. If we are to avoid making a mistake of selecting the wrong system, we must first have a clear view of the system we require. The system must contribute to facilities, speed and easę of use and the significant lessening of the workload of a pharmacist.It must offer the needed flexibility to amend certain areas according to the pharmacist's preference. It must be modular in structure and expandable so that module by module can be implemented according to convenience.

The functional requirements of a computerised system will vary depending on the type of pharmacy and its business objectives. For a retail or a wholesale pharmacy, the objective of introducing a computerised system is - to improve customer service. Therefore such units may look for a system that can provide for stock control, automated pricing routines, daily and monthly usage reports. The retail pharmacy may also look for drug information details like indications, dosage, interaction and contra-indications in their system which would be of immense help to the pharmacist. This can be omitted in a wholesaler's system as they are not involved in dispensing of medications directly to the patients.

Hospitals have many varied requirements. With the extensive use of medication in modern therapy, they have a need for highly skilled resources like experienced and knowledgeable pharmacists. The hospitals will need a system that can assist them to utilise these skilled resources in a better way. It is important to have a good labelling program which can give automated cautionary labels, drug interaction alert, and instant recall of previous labels. They need modules which can deal with inpatients and outpatients separately. Maintenance of patient medication profiles, assistance to the doctors by alerting them on drug interactions/allergy reactions or helping them in choosing the right type of drug and dosage.

SELECTION OF COMPUTER HARDWARE AND PROGRAMS :

For a small retail pharmacy, a microcomputer or personal computer would be sufficient. In such systems about 1000 to 1500 names of drugs, cautionary messages and lebels can be stored in the memory itself providing for quick response. Ready-made software is available which can provide complex facilities including already coded drug interaction warnings. Such systems are not expensive and will be sufficient in a single user environment.

In a large retail pharmacy where more than one outlet point exist to handle customers, a multiuser type of computer system may be preferable instead of using several single user systems. Multiuser systems can also serve for back office work like handling of accounts etc. However, the cost of multiuser system hardware and software will be much higher compared to single user systems.

It is most likely that large hospitals may develop their own programs because of their varied requirements.

While selecting a system, one should find out whether maintenance support is available locally.

CONCLUSIONS :

Computers can enhance the productivity and efficiency of a pharmacist. They can eliminate many manual procedures which reduce the amount of time available for them for performing the activities related to their profession. However, many pharmacies are not quick to adopt the technology and the potential of the computers to improve their efficiency remains untapped. With the availability of ready-made software and powerful personal computers which are not so expensive, even retail pharmacies should be able to consider computerised systems now.

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- THE PRODUCTS
- THE PHARMACISTS
- THE ORGANISATIONS
- THE MANUFACTURERS
- THE RETAILERS

Manufacture, Laws & Literature
Gives history and development of Pharmaceutical Industry; contains a chapter on Law pertaining to manufacture and sale of drugs; chapter on Pharmaceutical Literature and Films available for showing. At the end a list of Medical and Pharmaceutical Journals, published in India is given.

Pharmaceutical Directory
Contains details about Pharmaceutical Organisations, like Pharmacy Councils, Drug Control Administrations, Educational Institutions, and Pharmaceutical Associations.

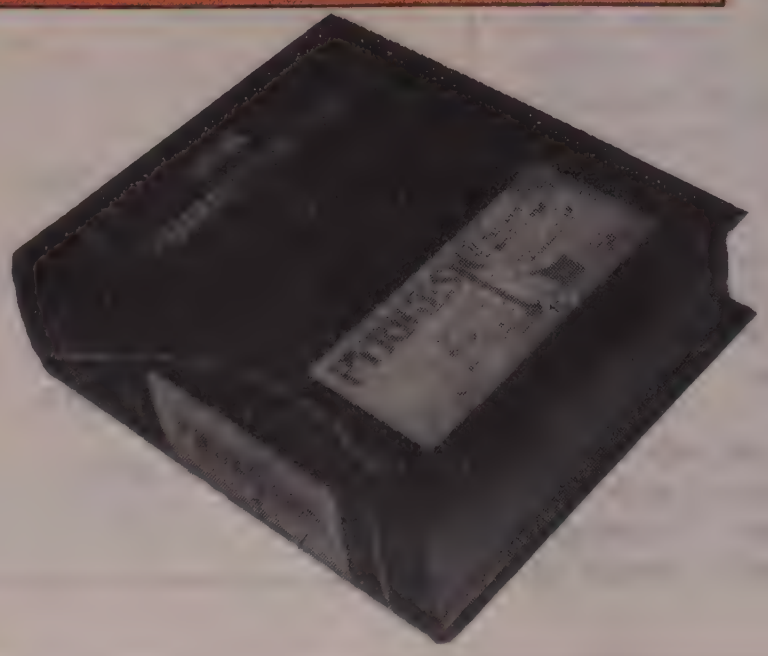
Pharmaceutical Distributors & Chemists & Druggists Directory
It gives details about thirty thousand Chemists & Druggists in India — State-wise — their addresses, nature of business whether retail or wholesale.

Pharmaceutical Manufacturers
Lists of all approved manufacturers of Pharmaceuticals who are licenced to manufacture drugs by various Drug Control Authorities of the country, with their full addresses and names of their products.

Allied Manufacturers & Dealers
Contains information about Allied Manufacturers e.g., producers of Chemicals, Pharmaceutical Machineries, Raw Materials, Packaging Materials, Surgical Instruments, etc. their addresses and names of the products they manufacture or sell. Information about Analytical Laboratories.

Products, Packings Compositions & Prices
This is most important section of the Guide. It gives details about Drugs and Pharmaceuticals produced by leading Pharmaceutical concerns. It lists the products with compositions, packings and prices, both wholesale & retail.

Cosmetics Manufacturers
List of all approved manufacturers of Cosmetics who are licensed to manufacture cosmetics by various Drug Control Authorities of the country, with their full addresses and names of their products.



Drug & Chemical Index
In this section the products are listed under Drugs and Chemicals headings according to major ingredients of the products formula.

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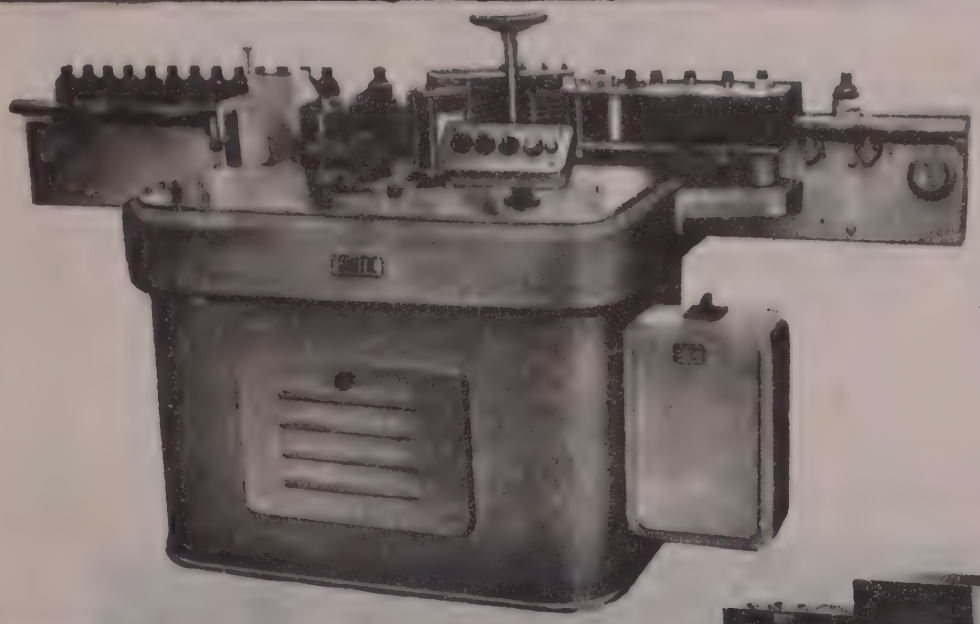
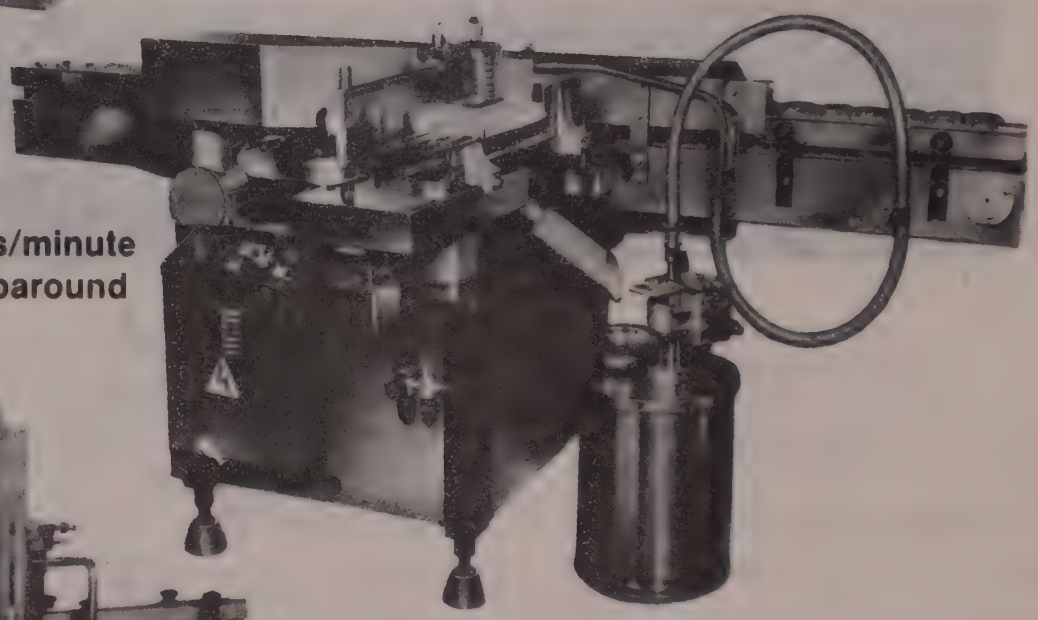


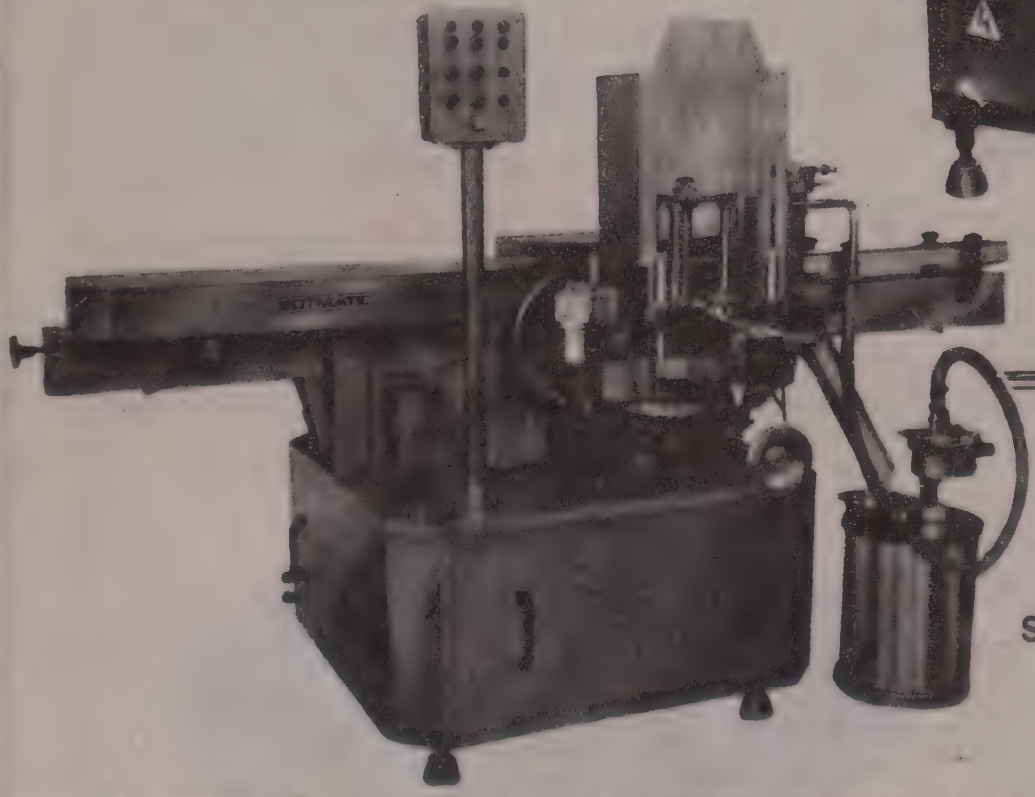
MINIMATIC

Object : Round/Flat
Output : 40-120 Containers/minute
Application : Patch Body
Size of Label : 15-120 mm.



ROTMATIC

Object : Round
Output : 100-200 Containers/minute
Application : Patch Body & Wraparound
Size of Label : 50-300 mm.



ROWMATIC

Object : Round/Flat
Output : 150-300 Containers/minute
Application : Patch Body
Size of Label : 15-140 mm.

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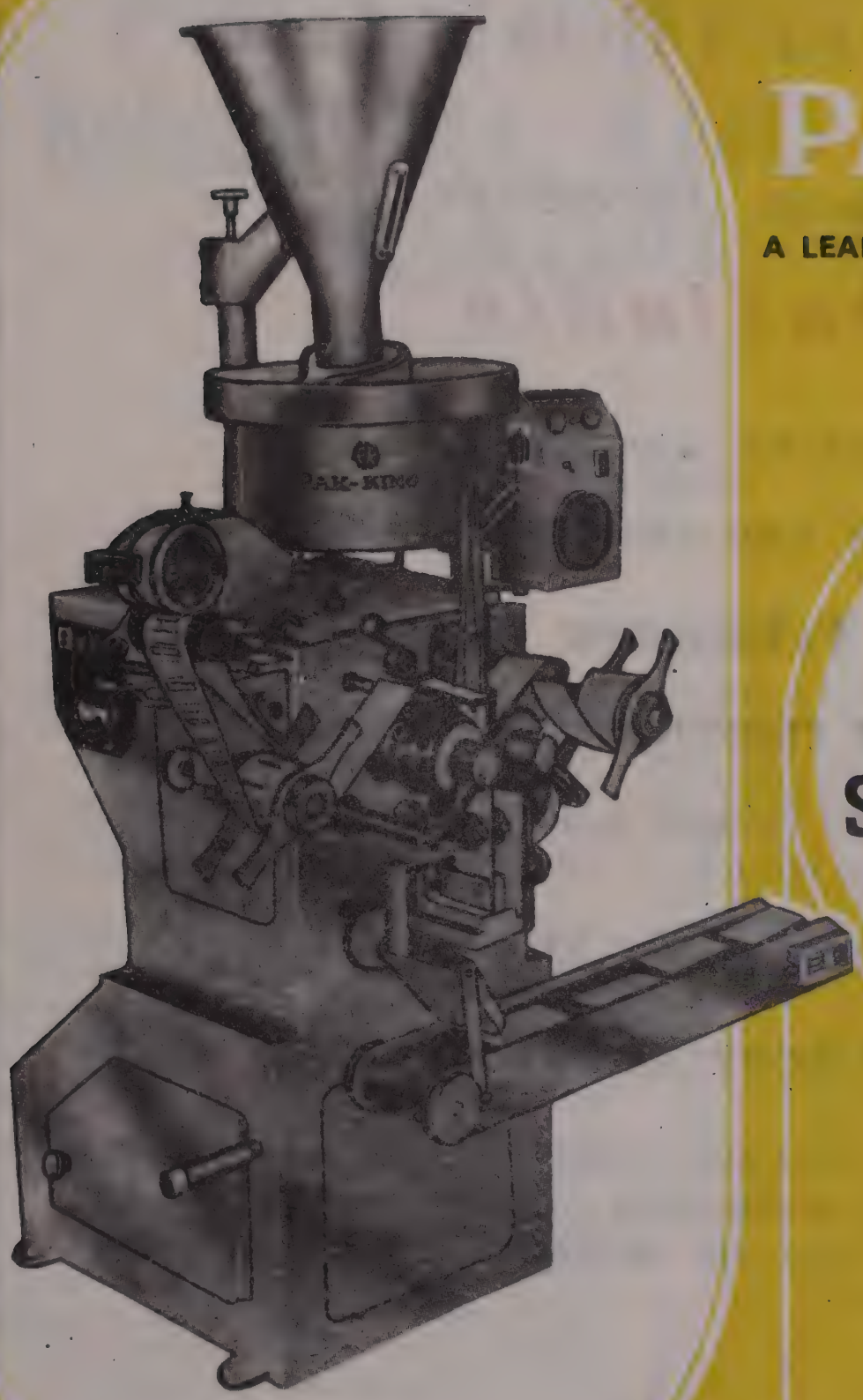

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Peter Marsh

BRITAIN'S biggest pharmaceuticals company, Glaxo, is constructing a £ 500 m research campus at Stevenage, 28 miles north of London. In the new laboratories, some of the cream of the world's drugs scientists will work surrounded by ornamental lawns and high-tech gadgetry in an effort to lay the foundations for the group's prosperity into the next century.

The new research centre illustrates the visionary, reflective side of the companies in the world's £ 70bn-a-year drug industry, which commonly spend up to 15 per cent of their sales on research and development (R&D).

The other face of the sector – which carries connotations of a more ruthless, expedient approach and a willingness to scrap for market share – was shown in another Glaxo move last month. A company reshuffle led to their resignation of its highly regarded chief executive of the past three years, Mr. Bernard Taylor. He was replaced by Mr. Ernest Mario, a hard-driving American executive. Mr. Mario was formerly head of the company's US operations and is considered within Glaxo as better able to guide the group through some of the tough times that might be ahead.

Although the drugs business often regarded as a glamour sector, it is also beset by problems.

● It is continually squeezed by government health agencies and insurance organisations. They are the main buyers for drugs, and they are stepping up their efforts to contain expenditure.

● The costs of pushing medicines through the development trials needed to satisfy regulatory authorities are rising. These procedures are becoming more onerous as a result of increased public interest in safety problems associated with new drugs. They can often take 10 years and cost up to £ 70 m for each new product.

● The researchers at the pure science end of the R&D pipeline – which accounts for roughly a quarter of total outlays and which is concerned only with ideas and experiments rather than with development trials – have in some ways been too successful.

Thanks to advances in scientific techniques such as biotechnology, and better management of research programmes, the number of new drugs being pushed on to world markets has been edging up.

The number, now running at about 50 a year, may well be up to 60 or 70 a year by the end of the century. Many of these products will not, however, be aimed at completely new applications but are more likely to be small advances on existing formulations, in areas of heart disease for example.

Mr. Mike Burstall, a UK healthcare industry consultant, says: "I wonder how many of the new drugs are going to recover their R&D costs." Due to the climate of cost-cutting among many of the big drug-purchasing agencies, room for expansion in the overall pharmaceuticals market may be limited to no more than a few per cent a year. That will place heavy pressure on the drug industry's sales staffs to crank out decent revenues from the new formulations.

Marketing is already a big financial burden on the drug companies. Unlike the research end of the product-development spectrum, which is highly centralised and conducted by closely knit teams, pharmaceuticals marketing is extremely fragmented. The industry relies for most of its revenues on convincing individual doctors that specific drugs are worth prescribing for their patients.

That entails employing large numbers of sales staff. To cover the whole of the US a big drug company would normally need 2,000 marketing personnel. The sales techniques used are tailored to the prescribing habits and the general cultural traits of the country in which the business operates.

Belgian doctors, for example, are thought to be highly susceptible to persuasion by drug companies about the merits of trying out a new product. Physicians in Britain and West Germany are said to be rather less easy to influence. Sales representatives from pharmaceutical companies try all manner of tactics to get doctors to listen to them – from free pens and notepads to all-expenses paid trips to exotic locations for lavish medicines conferences-and the approach may vary widely from country to country.

Drug companies are not the only ones to talk to doctors in an effort to change their prescribing patterns. In recent years public sector officials, especially in Europe, have made, much effort, as part of the general drive to cut government healthcare costs, to persuade physicians to prescribe more generic medicines. These are cheap copies of drugs which are off-patent and are usually cheaper than the branded formulation.

In most European countries, generic products already account for anything between 5 per cent and 20 per cent of the total market. Government pressure means that the proportion is likely to grow over the next few years. That will spell more difficulties for the big, research-based drugs companies which rely on branded products – and an opportunity for the smaller generics groups who do little of their own R&D.

In West Germany, Europe's biggest pharmaceutical market, the official policy on boosting generic products has already had one startling result. In recent months Ratiopharm, a small generics producer, has taken over the top spot in supplying the German market – ahead of Hoechst and Bayer, the two big research based German drugs groups.

Some say the industry's best answer to the high costs of R&D and marketing is to seek bigger groupings through mergers. That is one of the rationales behind the proposed Beecham/SmithKline Beckman merger which shareholders of the two companies are to vote on this summer.

A number of large European drugs companies, including Rhone Poulenc of France and Switzerland's Hoffmann-La Roche, have said they are interested in adding to their operations by acquiring US pharmaceutical groups. Companies said by analysts to be among possible targets include Warner-Lambert, Syntex and American Cyanamid.

But some observers are sceptical, "Bigness does not necessarily mean better," says Dr. Joe Zammit Lucia, a British pharmaceutical consultant. He thinks some drug companies may well shift in the opposite direction, deciding they have more to gain by "contracting out" key functions in either research, development or marketing to other groups.

There are already some signs of such moves, including the establishment of small, 100 per cent research-oriented drug companies – such as CNS Research in the US and Xenova in Britain – which aim to provide scientific expertise for some of the world's established healthcare companies. A large number of the dozens of biotechnology companies which have been set up in the past decade, especially in the US, may end up largely as producers of research ideas for the giant medicines companies.

At sales end of the industry, Marion Laboratories has gained prominence in the US as a drugs company wholly geared not to research but marketing. It does nothing else but sell prescription products devised in the research laboratories of other groups.

Straightforward licensing deals are also on the increase. They are a particularly flexible way of extending a drugs company's international operations. In such arrangements, a business can either use its sales force to market another group's product or give another organisation the rights to sell its own drug in exchange for a royalty.

Big Japanese drugs companies such as Takeda and Yamanouchi have generally refrained from building up their own marketing forces in the West and have relied up to now on licensing deals as a way of getting Japan. that may, however, be changing as many of the Japanese companies step up R&D investment and start to use biotechnology to devise new products which could have large sales potential. Many believe the Japanese companies will try to do more to extend control over their overseas operations, possibly by employing their own sales teams. "They are on a fast learning-curve," says Mr. Hans-Peter Sigg, vice president of Sandoz, the big Swiss pharmaceuticals company.

As well as widening their marketing reach, companies are also likely to try in increase the geographical scope of their R&D. This seems especially likely with Hoechst and Bayer and Ciba-Geigy of Switzerland, which are generally agreed to have had little in the way of research success in recent years. Setting up laboratories in either the US or Japan – something which all three companies are doing – may be a way of exposing their researchers to new ideas and possibly prodding them into coming up with world-beating products. The three groups-and Britain's Imperial Chemical Industries – have an advantage in being parts of large integrated chemicals companies. Thus any poor times in their drugs businesses may be offset by better profits and sales in other operations.

As for production, not much is likely to change. The cost of many of the raw ingredients in medicines is fairly low and the

manufacturing processes needed to turn these chemicals into pills or lotions are not particularly demanding, either in terms of plant or manpower.

As a result, much drug manufacturing is organised on what appears an irrational basis. Plants are spread around different markets and are working well below capacity. This is especially marked in Western Europe, where the different national health agencies often let drugs suppliers charge higher prices if they have local manufacturing facilities. The power of these agencies to influence local manufacturing practices will, many observers think, remain strong even after the planned completion of the European single market in 1992.

To escape from their dependence on the spending decisions of frugalminded public authorities or insurance organisations, some drug companies are tending to take products out of the prescription field and into the straightforward retail market. The "over-the counter" end of the drugs market accounts for only about 10 per cent of overall sales-although the proportion is significantly higher in the US – and room for growth may not be particularly high. That has not stopped a number of companies, including the proposed Smith-Kline/Beecham grouping and Wellcome of the UK, from eyeing this as a possible place for expansion.

Merck, which intends to remain solely a prescription-drugs business, has agreed on a deal under which Johnson & Johnson, another big Us drugs group, will revamp promising Merck prescription products and turn them into formulations which can be sold through retail outlets. One product which might be so transformed over the next five years in *Mevacor*, which is now available only through a doctor. It reduces the cholesterol build-up in the arteries which is behind some types of heart disease.

Over the next few years, the industry will probably develop by combining all these approaches. There will be a certain amount of industry rationalisation through mergers and companies going out of business, together with more imaginative use of marketing and research joint ventures.

Permeating all these initiatives will be the recognition that the pharmaceuticals industry – which in tackling the ailments afflicting the human race is not short of challenges already – must face up to non-physiological problems that are just as taxing.

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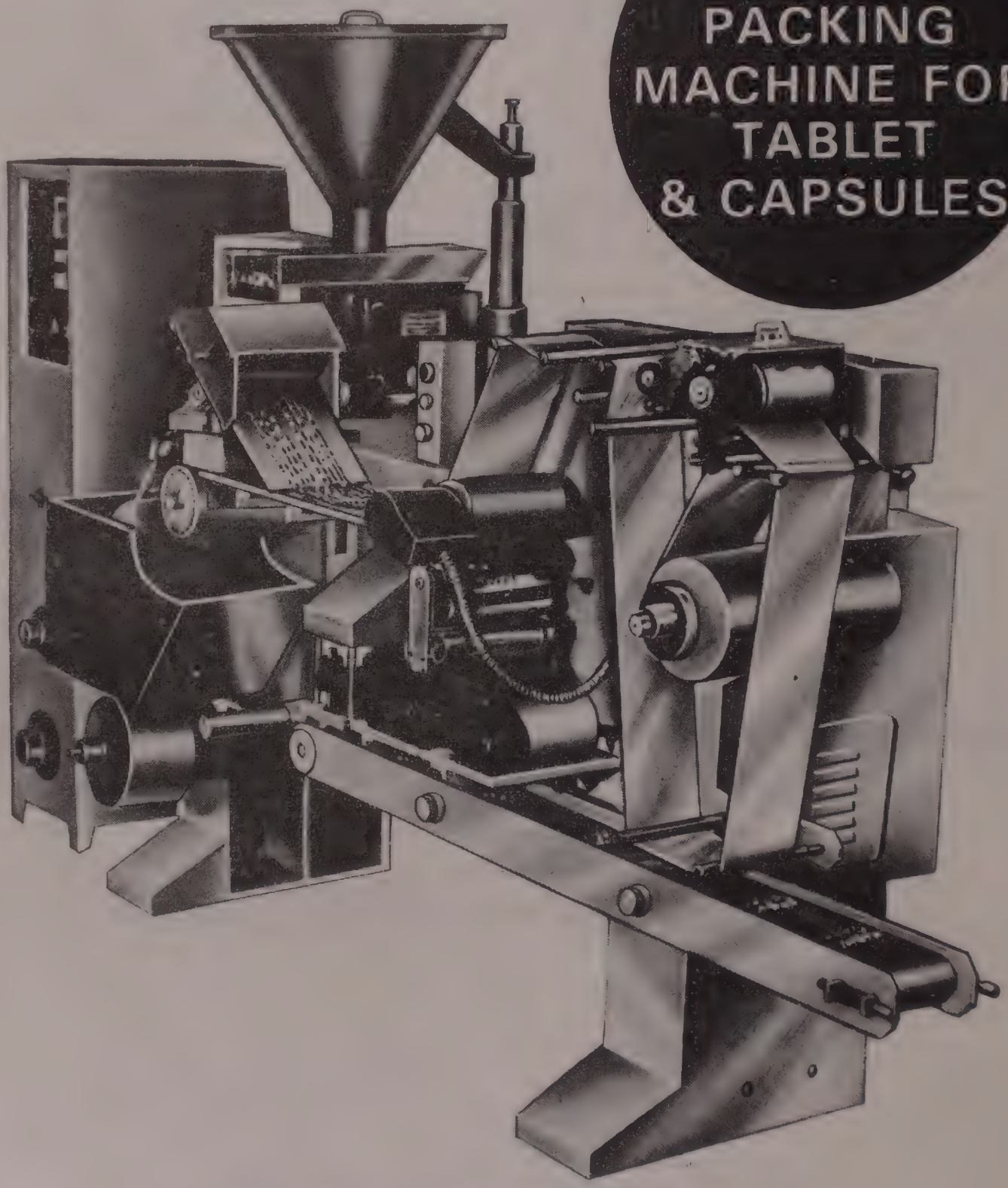

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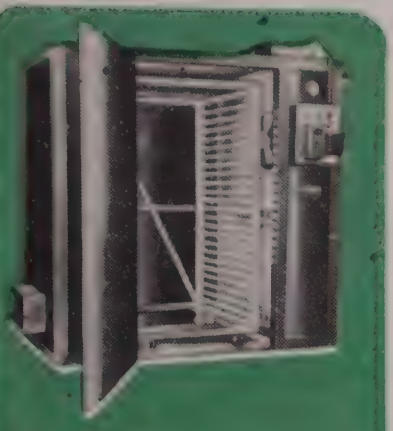
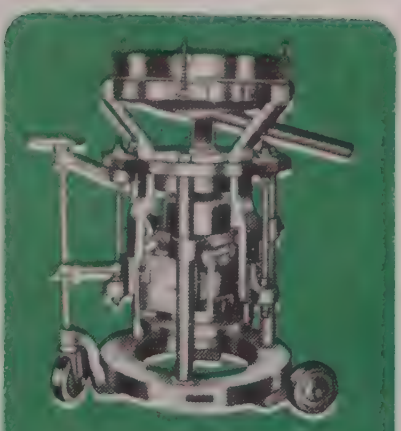
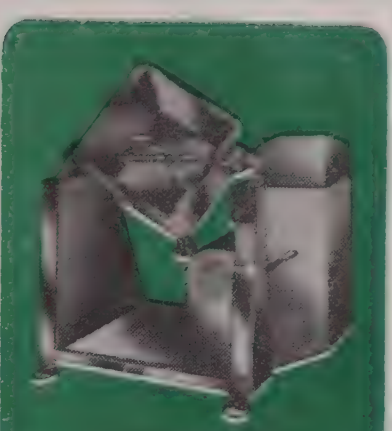


HOT AIR DRIER



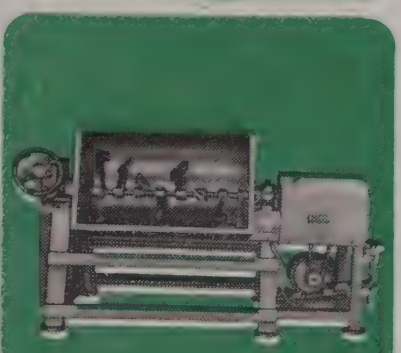
SIFTER



ROTO CUBE BLENDER

MULTI MILL

COATING PAN

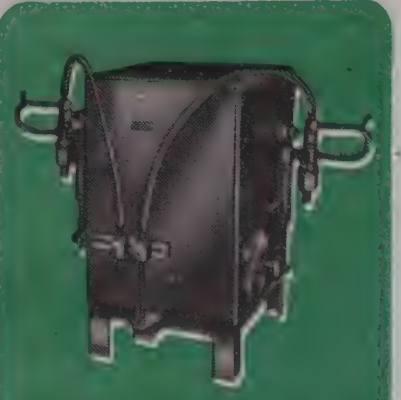


POWDER MASS MIXER

REACTION KETTLE

HORIZONTAL PLATE TYPE FILTER PRESS

PLANETARY MIXER



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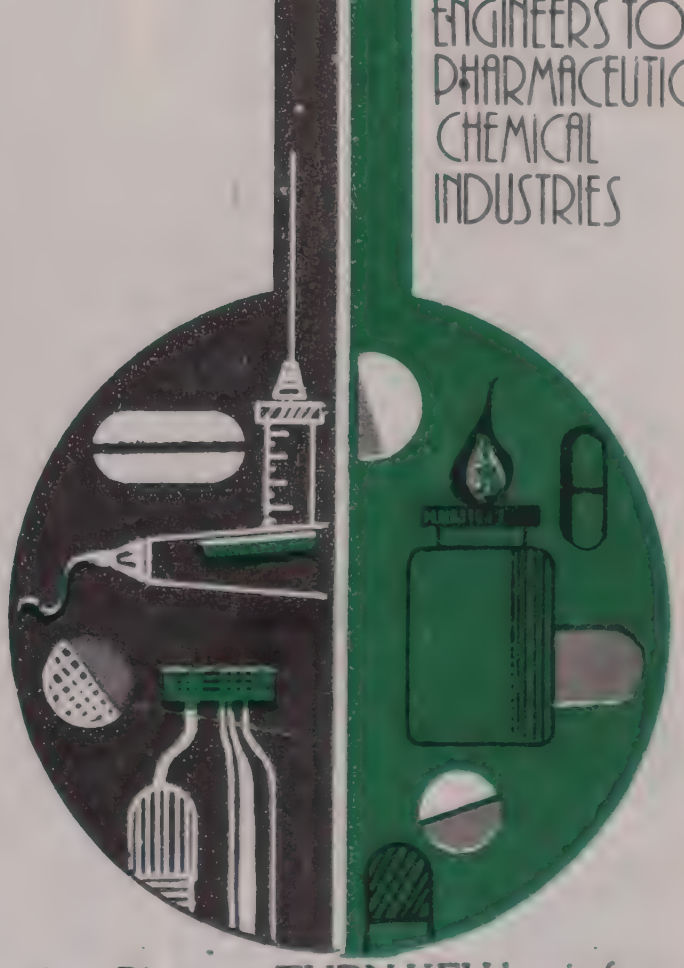

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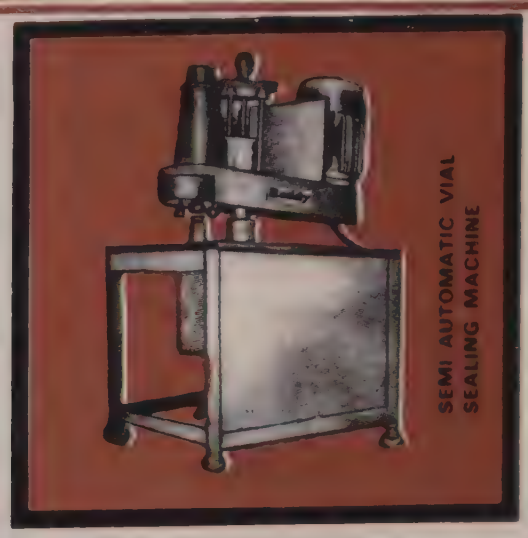
JET TYPE AMPOULE WASHING MACHINE (AUTOMATIC)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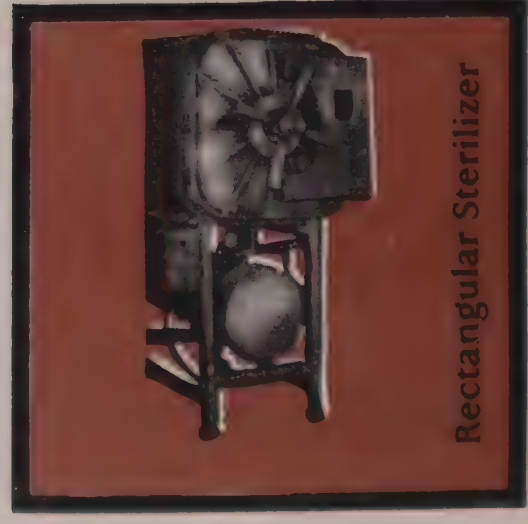
Rectangular Sterilizer

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P.C. Ray Award For Ranbaxy

DEVELOPMENT OF INDIGENOUS TECHNOLOGY IN DRUGS

Special Correspondent

RANBAXY is today in the forefront of the Indian Pharmaceutical Industry, committed to providing products and services of the highest quality in the area of Health Care. Its total approach to healthcare is reflected in the wide range of its products - Pharmaceuticals, basic drugs, animal health care products, surgical dressings/bandages and diagnostics kits and instruments.

Ranbaxy's focus on quality is clearly visible in its six plants-two formulations plants located at Okhla in New Delhi and Dewas in Madhya Pradesh; two chemical plants located in Punjab at S.A.S Nagar (near Chandigarh) and Toansa (Distt. Hoshiarpur); the surgical dressings and bandages plant located at Dewas in Madhya Pradesh and the diagnostics facility at Okhla in New Delhi. The pharmaceutical plants are accredited by WHO and ensure products of the highest quality fully in consonance with international standards. The Toansa bulk drug plant has been approved by FDA of the USA and is truly a symbol of quality and reliability. The surgical dressings and bandages facility employs the latest 'state-of-the art' technology.

Research at Ranbaxy is a deep-rooted culture springing from the belief that only a continuous quest for the best would lead to products of the highest quality. In keeping with its commitment, the company established a separate R&D Division as far back as 1973. Today, over 100 scientists are engaged in various disciplines at the company's research centre at New Delhi supported by the latest facilities and instrumentation in an environment conducive to productive research. The group has done pioneering work in the indigenous development of technology manufacture of newer generation essential drugs including antibiotics, anti-bacterial and anti-ulcerant drugs. This research orientation has provided a base for the Company's sustained growth with products such as Doxycycline Hyclate, Ampicillin Trihydrate, Cephalexin

CITATION

RANBAXY Laboratories Limited have pioneered the introduction in India of a number of important drugs, involving high technology. The production of Anti bacterial Doxycycline Hyclate involves hazardous chemicals and complicated reactions, involving stereospecific sysnthesis. The other important drugs from the house of Ranbaxy include Ranitidine, Norfloxsacin and Nalidixic acid. The innovative technologies developed by the company have enabled them to export drugs even to the develped economies.

In recognition of these achievements sustained over a protracted period, in developing highly innovative technologies from basic raw materials, involving complex organic chemistry and difficult engineering, the Indian Chemical Manufacturers Association is happy to confer the I.C.M.A. Acharya P.C.Ray AWARD FOR DEVELOPMENT OF TECHNOLOGY INDIGENOUSLY for 1988 on Ranbaxy Laboratories Limited, New Delhi.

Bhai Mohan Singh

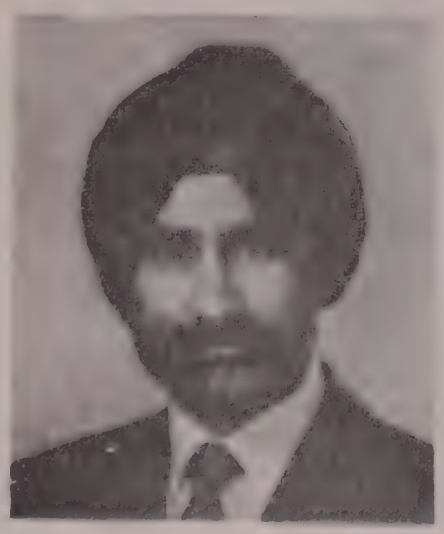
From financial business to pharmaceuticals looks a far cry, but with a few lucky breaks and sheer hard work, Bhai Mohan Singh has achieved this over a span of over 25 years.

His leading pharmaceutical company Ranbaxy Laboratories Limited with exports to about 40 countries, has an annual turnover of Rs. 148 crores. The target for this year is Rs. 180 crores.

Ranbaxy, along with marketing bulk drugs and finished products has also set up joint ventures in three countries – Nigeria, Thailand and Malaysia.

It is Dr. Parvinder Singh, a technocrat, who as Managing Director of Ranbaxy is looking after the operations of the giant pharmaceutical company, one of the biggest in India. His concerted efforts and efficient leadership has put the company where it stands to-day.

Dr. Parvinder Singh



monohydrate, Nalidixic Acid, Norfloxacin, Ciprofloxacin and Ranitidine Hydrochloride.

Ranbaxy has achieved a leadership status in the pharmaceutical industry in India through a philosophy of concentrating in therapeutic segments of significant relevance not only in India but the developing world. A vibrant and responsive marketing group is the key to translating research achievements into marketing success. Ranbaxy's products today are brand leaders in all the segments that the Company operates Rocillin(Ampicillin), Sporidex(Cephalexin), Gramoneg(Nalidix Acid), Norbactin (Norfloxacin),Cifran (Ciprofloxacin), Histac(Ranitidine Hydrochloride) Calmpose (Diazepam) and Fortwin(Pentazocine).

The company's marketing team disseminates scientific and clinical information about the Company's products through its 800 medical representatives to over 80,000 doctors in 3000 towns. Further, through an extensive distribution network, it services 45000 retail outlets throughout India.

Ranbaxy's domestic achievements and research capabilities are fully reflected in its export achievements consistently through the last few years. In Ranbaxy, exports mean more than just sale of goods to a foreign market. It includes sharing of marketing and technological expertise with its partners the world over. The international operations have concentrated their efforts on long term goal which have helped Ranbaxy achieve a dynamic presence in over 30 countries. The Company's exports from India have continued to grow each year and touched a new height of over Rs. 355 million in 1988-89, mainly in free foreign exchange. Ranbaxy has been the recipient of several exports awards by the Chemexil Council in the last five years including the "Trishual" Award for the year 1987.

Ranbaxy is successfully operating joint ventures in Nigeria (Ranbaxy Laboratories(Nigeria)Ltd.,) Malaysia (Ranbaxy malaysia Sdn.Bhd.), and Thailand (Ranbaxy Thailand Co. Ltd.,). It has marketing offices operating at Sin-

Praful Sheth , Vice-President

gapore and Cameroon. The quality of Ranbaxy products, backed by a strong and advanced technological base, has enabled Ranbaxy not only to successfully compete in the international markets for vital bulk drugs but also helped in the national import substitution efforts.

Ranbaxy has been awarded the prestigious Indian Chemical Manufacturers association Acharya P.C. Ray Award for the development of technology indigenously. This award is a recognition of the Company's continuous quest for excellence and self-reliance in high technology areas through the development of technologies for Ranitidine Hydrochloride, third generation antibacterial Fluoroquinolones and new proceeses for Doxycycline Hyclate.

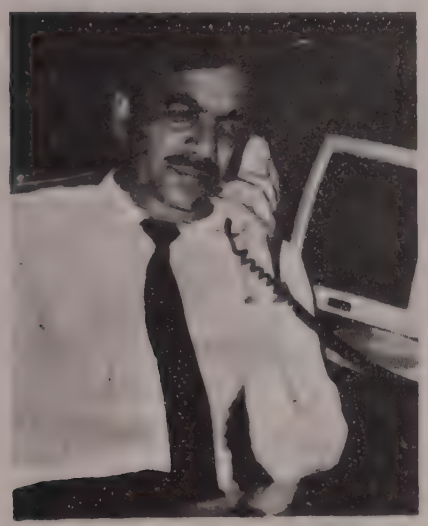
Ranitidine Hydrochloride is used in the treatment of peptic ulcer. The process know-how for its manufacture involves multisteps complex chemical reactions and is, therefore, categorised

J. M. Khanna, Director (R & D)

as a high technology area. The entire plant with capacity of 30 tons per annum worth Rs. 2 crores has been designed indigenously.

The manufacture of Doxycycline Hyclate is a highly hazardous process since it involves the use of dry hydrogen fluoride and hydrogenation. Ranbaxy's in house research team has developed a novel catalyst which possesses unique activity. As a result, Ranbaxy has overcome the problem of existing process patents in the developed nations and it is currently exporting almost 80 per cent of the production to such countries. Several process patents have been filled in India and abroad.

K. L. Khurana (Bulk Drugs)



R & D Laboratory Of Ranbaxy

Ranbaxy was first company in the the country to manufacture Norfloxacin and Pefloxacin from basic stage. These technologies involve complex chemical reactions in their manufacturing processes. Almost 50 per cent of the Company's production is exported.

Ranbaxy is one of three manufacturers in the world and the only one in India of Nalidixic Acid.

Ranbaxy's technology has resulted in higher yields than that reported in chemical literature with product quality in line with international specifications.

With high quality products, the Com-

US FDA Approved Antibiotics Plant Of Ranbaxy

With the emergence of Fluoroquinolones as third generation anti-bacterials the concept of infection management has taken a new turn. Fluoroquinolones like Ciprofloxacin, Norfloxacin, Ofloxacin, Endxacine, etc, are today the leading potent anti infectives and have been introduced in the market only in the last 2-3 years.

In keeping with contemporary development, Ranbaxy has initiated activity in this field and has indigenously developed know how for the manufacture of the following drug: Ciprofloxacin, Norfloxacin, Pefloxacin Nalidixic Acid.

Ciprofloxacin is the most recent introduction in the range of fluoroquinolones. The entire production is currently being exported.

pany has been able to successfully compete in international markets. Additionally, the Company's export activity has been given a major fillip especially in the developed economies. The Company has not only been able to establish a leading name for itself in highly competitive international markets but also been able to reduce the value of imports as also become a net exporter, which has contributed to the foreign exchange earnings of the country.

Expansion & Present Working

Ranbaxy, which is a leader in bulk antibiotic drugs and formulations, has decided to venture forward in the field of biochemical, anti-bacterial drugs and vitamins. The company is investing around Rs. 4 crores annually in R & D where new drugs like norfloxacin, ranitidine, an anti-ulcer drug which is the world's largest selling, perioxacin and efloxin have been developed. The last two drugs are being totally exported at present. Inquiries from China and Russia have also been received for these drugs.

The company has also developed an anti-infective drug, ciprofloxicin which is a substitute for antibiotics. It is presently being exported to Europe, China and Japan. The Indian government's approval for marketing the drug in the country is also likely to be received this month. The company's bulk drug plant at Toansa in Hoshiarpur district of Punjab has been approved by the Food and Drugs Administration of the U.S.A., which has led to the opening of new export vistas in the world largest pharmaceutical market. With its recent breakthrough based on its own technology, the company has earned a place among the world's technologically advanced pharmaceutical companies.

With exports at over 50 per cent of its total production of bulk drugs, it has earned foreign exchange to the tune of Rs. 34 crores in the 15 month period ended March 31, 1989, against Rs. 18.33 crores in 1987. The company has, however, set a still higher export target of Rs. 40 crores for the current year ending March 31, 1990, which it expects to exceed in view of the buoyant demand for its products in overseas markets.

Meanwhile, the company has made good progress in its Rs. 17 crore expansion and diversification programme. The computerisation of its manufacturing facilities and outlets have become operational, thus optimising its operations. The on-going capital expenditure on the research centre has also been fully utilised. The expansion of the surgical dressings and bandage unit at Dewas in M.P. has become fully operational.

The first phase of the expansion of the clinical diagnostics unit at Okhla, New Delhi, has gone on stream and the second phase is expected to be completed by December 1989. The basic drugs plant for the new drugs unit at Shaibzada Ajit Singh Nagar has also gone on stream.

In the 15 month period ended March 31, 1989, the company has achieved sales of Rs. 179 crores against Rs. 112 crores in 1987, thus recording a growth of 32 per cent on an annualised basis. The company has also shown a commensurate increase in its profitability. With large investments in 1988-89, the depreciation charge is expected to be substantially higher, taxation rates much lower and net profits higher, The company has already paid an interim dividend of 15 per cent for 1988-89 and is likely to recommend a reasonable final enquity dividend when the accounts for the 15 month period are finalised.

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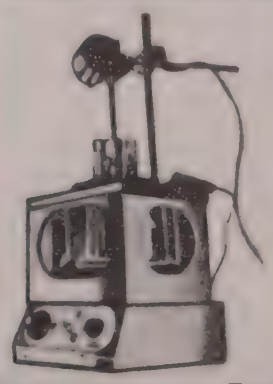
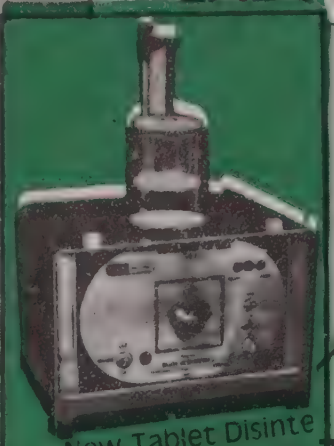
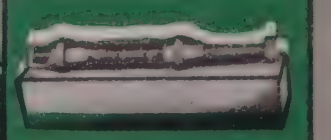
PHARMACEUTICAL MACHINES & LABORATORY EQUIPMENTS



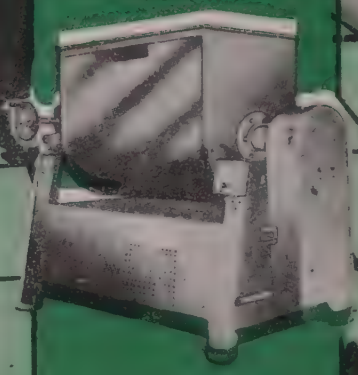
Dissolution Rate Test Equipments (u.s.p.) XIX-XX-XXI



New Tablet Disintegration (I.P. 1985)

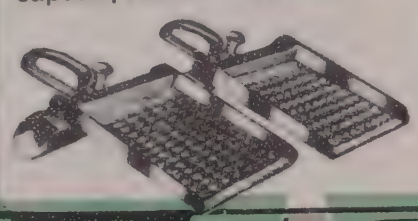


Tablet Hardness Tester

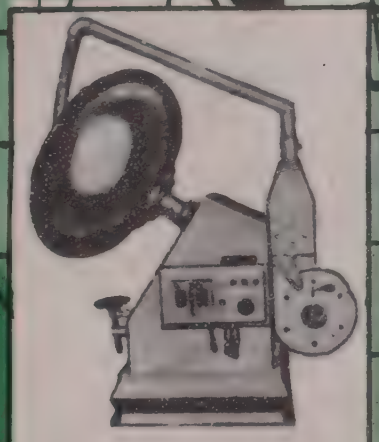


Powder Mass Mixer

Capsule/Tablet Counters



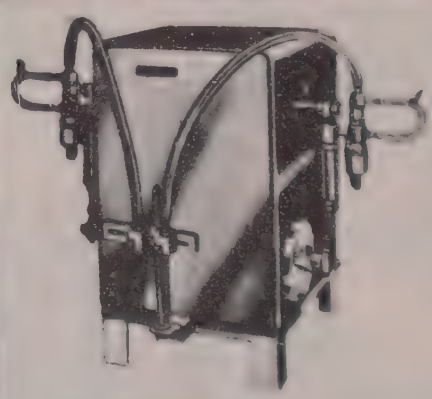
Hot Air Oven



Coating Pan

Multimill

Foot operated Filling Machine



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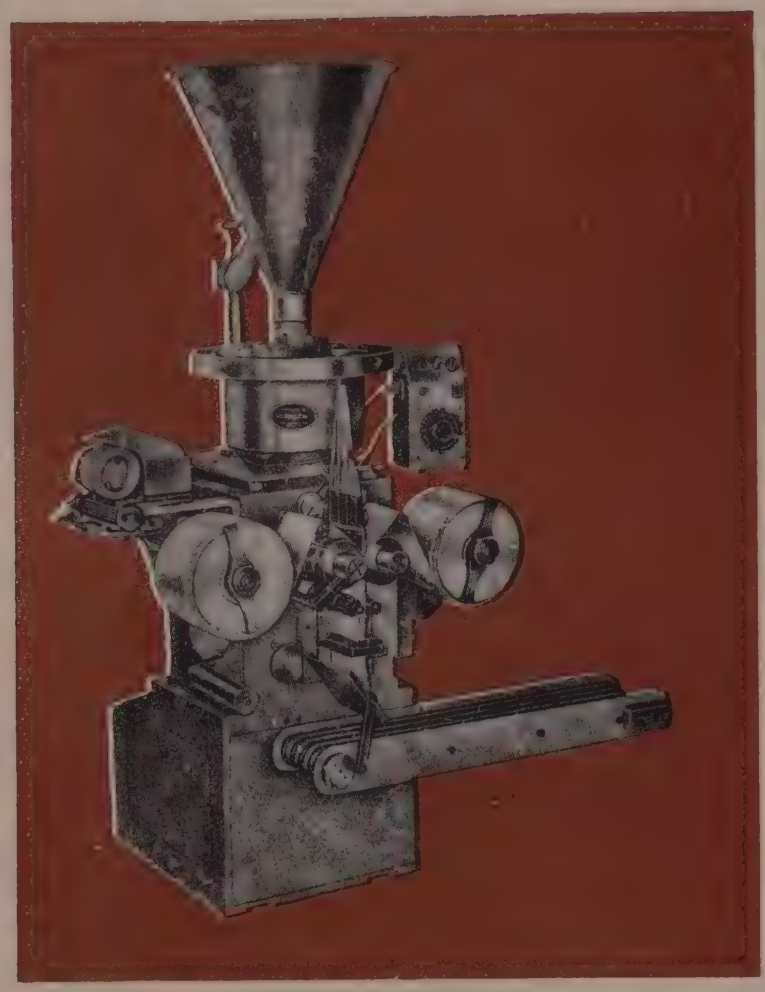

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SCREENING OF MEDICINAL PLANTS WITH ANTIFERTILITY AND SPERMICIDAL ACTIVITIES

Dr. N. Udupa,
College of Pharmacy, Kasturba Medical College, Manipal -576 119.

The antifertility activity of many medicinal plants are mentioned in Ayurvedic literature and few of them are presently being successfully used for the control of fertility and it is also claimed that these plant medicines are safer than synthetic compounds. Indigenous plants for which antifertility activity has been reported, should be further subjected to studies to establish the chemical identity of active components and to investigate their biochemical and pharmacological aspects. Qualitative and quantitative tests of active constituent may be performed using modern analytical tools like U.V. - Visible, I.R. spectroscopy, NMR, G.C., HPLC, HPTLC techniques.

Isolation, Identification And Phytochemical Evaluation :

Different solvent extracts of various parts of plants are to be prepared and detailed phytochemical investigations should be done to identify the structure of active constituents. Suitable extraction, isolation and purification steps should be undertaken to prepare substantial amount of active components. Possible derivatives of active components can be prepared and subjected to different physicochemical tests. These compounds and extracts should be subjected to evaluation of antifertility activities in animal model using mice, rats, rabbits and dogs. Attempt should be also made to establish structure activity relationship.

Biochemical Studies :

After administering the plant extracts and derivatives of antifertility drugs with maximum activity various biochemical functions should be studied. The hormonal levels should be studied in animals after administration of antifertility drug and compared with control experiments without antifertility drug. The levels of alpha foeto protein, chorionic gonadotropine, progesterone, leutinizing hormone, follicle stimulating hormone, prolactin etc. can be measured by suitable radioimmunoassay methods using animals [15,33,34].

The antifertility activity of plant extract can be also compared with oral contraceptives like ethinylestradiol and norethisterone. For comparison of antifertility activity, the biochemical functions, pharmacodynamic and pharmacological action, hormonal levels in blood and urine, extent of toxicity and side effect may also be considered. The levels of immunoglobulin hormonal and metabolic serum parameters of healthy animals and volunteers may help in evaluating the effect [12,13] of antifertility extracts of plants. The effect of uterine endometrium is also very useful[14]. The haematological tests like amount of haemoglobin, total leucocyte counts, differential leucocyte counts, ESR, biochemical tests like renal and liver function tests, blood sugar, hormonal progesterone levels should also be monitored[16]. The effects on oestrous cycle, implantation, foetal loss or development, plasma estadiol levels, overian function, endocrinal morphology etc. are also useful.[19,34]

The spermicidal activity of plant extracts in rats/human semen at 2% concentration can be determined as per the methods of Shetty, Kamboj, & Khanna[3]. Biochemical, histochemical and histological studies of effects of extracts

from plants can be done on the testes of adult albino rats.[42]

Pharmacological & Toxicological Evaluation

The reproductive biologist should screen any antifertility compound for reproductive effects in animals. After achieving the desired activity, during establishing the structure activity relationship, additional screening tests for reproductive activity and other pharmacological activity should be conducted.[44]

These screening tests include-testing for cardiovascular, C.N.S. gastrointestinal activities and endocrine profile i.e. estrogenicity by uterine weight method and vaginal cornification methods.[45-48], progestational test[49], antiprogestational anabolic test[50], antiestrogenicity by uterine weight method[51] and antiestrogenicity vaginal cornification method[52], antigonadotropin test53, progestin receptors, estrogen receptor[55], Corpus lutuem progesterone production[5, 57] Mcginity test[58] etc.

The antifertility compound has to be selected based on its potency, toxicity, specificity or selectivity, onset and duration of action and route of administration and its stability in formulation, and cost of extraction from plants or production.

Further the isolated antifertility drug from plant should be subjected to reproductive pharmacological studies in nonprimate and primate species. The possible mechanisms of action should be elucidated. the gonadotropin suppression studies should be conducted in several species like rodent and non-human primate like monkey or bàboon. The effect of antibertility plant extract on the reproductive organ can be evaluated histologically. Receptor binding assays for LH could be done at this stage. The degree of antifertility activity in non-human primate such as baboon can be conducted and time dose response studies can be performed to assist in choice of future human dose. The possible toxicity and side effect if any should also be established systematically.

Suitable formulation should be worked out and stability study of drug in various stress condition should be performed. Afterwards absorption and pharmacokinetic parameters should be worked out. Cost of production, raw materials and packing materials should be worked out. The safety of drug/dosage form should be carefully assessed. Toxicological studies in animals - by acute studies subacute studies and chronic toxicity studies in rats, dogs and moneys should be undertaken and teratological studies, perinatal and postnatal studies should also be undertaken. Expanded clinical trials may begin following completion of all animal experiments. The long term studies and evaluation of carcinogenicity if any also should be conducted before introducing the dosage form to the market.

Plants Having Antifertility Activity

1. Moringa Pterygosperma & Oleifera [1-4,31,32,36-]
2. Cucurbita Maxima[5]
3. Triumfetta rhomboidea[6,7]
4. Echonops echinatus[8,30]
5. Ferula foetida & Jaeschkeana[9,10]
6. Aristolchia indica[11]
7. Azadiracta indica[11]
8. Anona squamosa[9,10]
9. Butea monosperma[11]
10. Luffa echinata[9,10]
11. Vicoa indica & vestita (Banjauri)[10,16-18]
12. Cuminum cyminium[19-25]
13. Artemisia absinthium[26]
14. Schuberia multiflora[26]
15. Allium cepa[27-29]
16. Juniferous communis[10,31]
17. Acacia furnesiana[10]
18. Acrostichum aureum[1-4]
19. Bupleurum marginatum[9]
20. Chonemorpha fragrans[9]
21. Geum elatum[1-4]
22. Ipomea pes-caprae[9]
23. Lamium album[1-4]
24. Lepidium capitatum[10]
25. Lonicera Japonica[10]
26. Perilla frutescents[1-4]
27. Pluchia lanceolata[9]
28. Pulicaria angustifolia[9]
29. Virbena bonariensis[1-4]
30. Zingiber roseum[10]
31. Amorphophallus campanulatus[10]
32. Carex inanis[10]
33. Coconopsis wata[10]
34. Cydonia oblonga[10]
35. Deutzia Corymbosa[10]
36. Ephedra gerardoama[10]
37. Geranium lucidum[10]
38. Gnaphallium peusylvanicum[10]
39. Heraclenen thomosonii[10]
40. Hippophae rhamnoides[10]
41. Luffa echinata[9]
42. Polemanium coevuleum[9]
43. Thalictrum cultratum[9]

Plants Having Spermicidal Activity : [1-4, 35, 42]

1. Aesehynomene india
2. Albizzia lebbeck
3. Anisomeles Malabarica
4. Arclisia neriifilia
5. Calhta palustris

6. Clerodendrum Serratum

7. Dimeria gracilis

8. Gypsophila cerastioides

9. Madhuca butyraca

10. Pittospozum nilghirense

11. Pterolobium indicum

12. Samanea saman

13. Sapindus mukorossi

14. Schefflera capitata

15. Solidago virga aurea

16. Symplocos gardeneriana var hehenacheri

17. Trigonella foenum - greacum

18. Calamintha umbrosa

19. Calendula officinalis

20. Celcia coromandeliana vahl

21. Celastrus paniceuloctus

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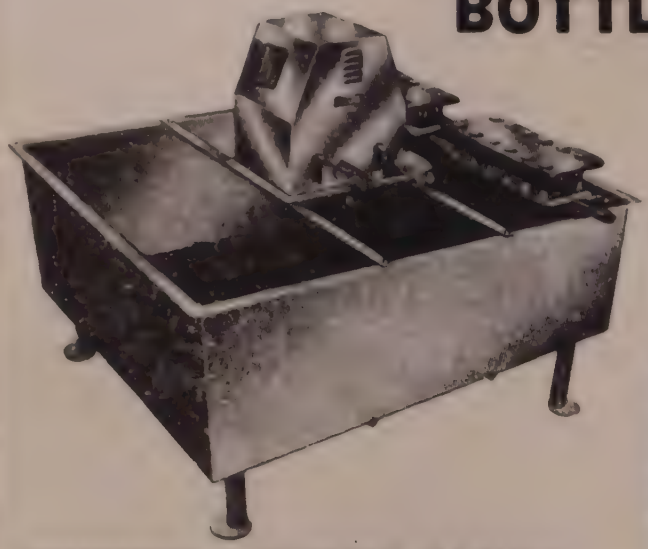

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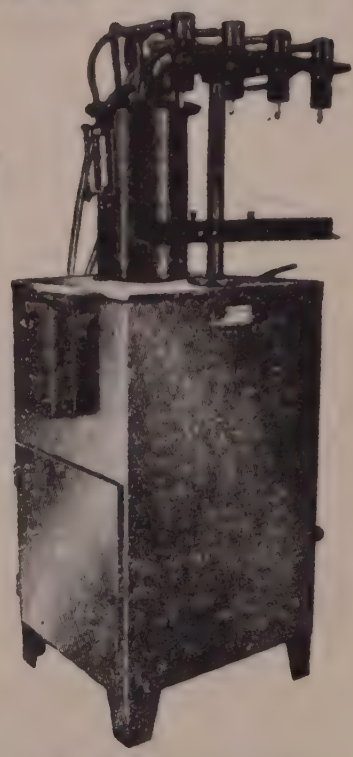

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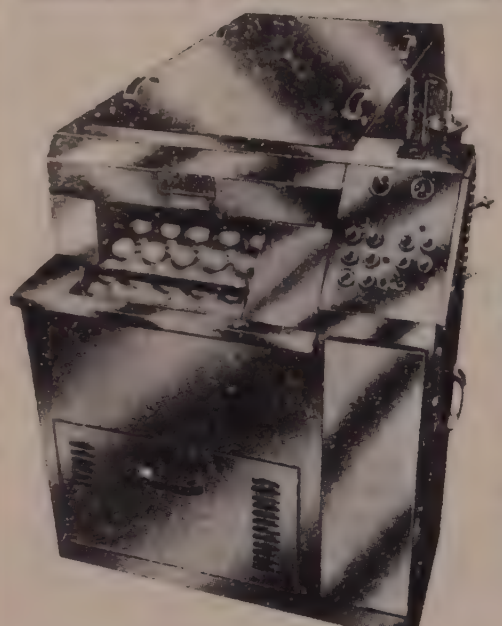

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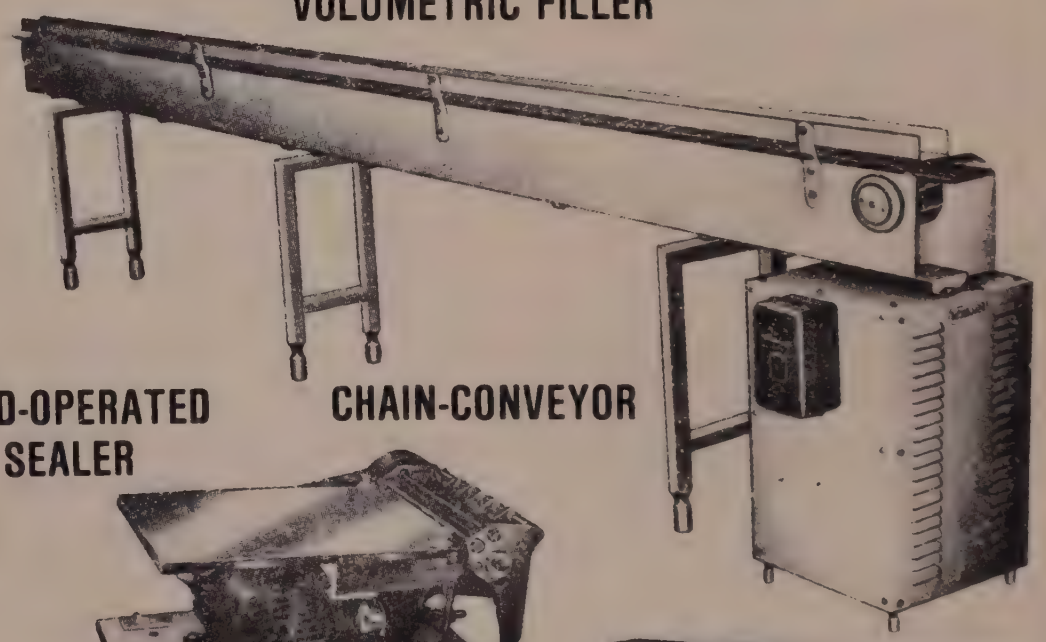

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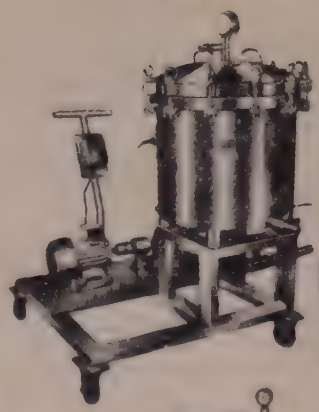

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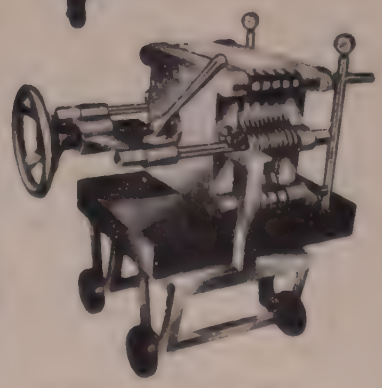

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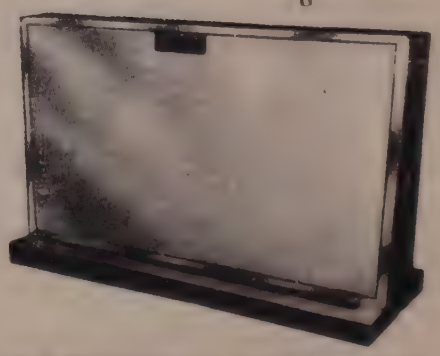

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TYPICAL/88

GOOD MANUFACTURING PRACTICES

Dr. M.A. Patel,
Food & Drugs Control Administration, Gujarat State, Gandhinagar.

The concept of Good Manufacturing Practices is known to all concerned with the Pharmaceutical Industry. The people working in different facets of Pharmacy such as production of pharmaceutical formulations, teaching in Pharmacy, enforcement of the Drugs and Cosmetics Act, 1940 and Rules thereunder, marketing of drugs, sales and distribution of drugs, etc. all are working in the interest of patient or we may identify the patient as a consumer. Jokingly some people interpret Good Manufactufirng Practics as 'Give More Production'. But, that is also true in the sense that when Good Manufacturing Practices are observed strictly, no rejection will be there, resulting in increased production. It can be identified to get more profits also by reducing the rejections and getting more yield.

In Pharmaceutical Industry total control of quality should be plant wide activity and should represent aggregate responsibility of all segments of the company. Good Manufacturing Practices provides specific guidelines to serve as checks for critical operations within the entire organisation so that a total quality control system can be achieved.

It is important that production and quality control should be kept separate and equal, and head of both the departments should report to same executive i.e. Plant Manager. The quality control alone should have ultimate responsibility for removing a product at any stage in its processing into or from quarantine or to into rejection status. Information from production should be utilised in arriving at the decision, but authorities must be centralised and separate from production.

In the manufacture of drugs over all control is essential to ensure that the consumer i.e. the patient receives drugs of best quality. Haphazard operations cannot be permitted in the manufacture of substances that may be necessary to save life or to restore or preserve health.

Difficulties will undoubtedly arise in establishing the necessary criteria for manufacture of drugs that will meet established specifications and that can, therefore, be used with confidence. Recommended practices for the manufacture of drugs of desired quality are described as Good Manufacturing Practices. Adherence to these practices, complementing the various control tests followed from the beginning to the end of the manufacturing cycle, will contribute substantially to the manufacture of consistently uniform batch of best quality drugs.

The manufacturer must assume responsibility for the quality of the drugs he produces. To meet with the fixed standards is not voluntary, but obligatory on the part of the manufacturer.

Just like western countries, now Good Manufacturing Practices are made part of the legislation in India. The details are as under:

GOOD MANUFACTURING PRACTICES IN PHARMACEUTICALS

The Drugs & Cosmetics Act was enacted by the Government in our country in 1940 while the Rules under the said Act were framed in 1945. Thus, the Act and Rules are known as Drugs & Cosmetics Act, 1940 and Rules thereunder. This Act regulates the import, manufacture, distribution and sale of Drugs and Cosmetics.

When the enforcement of this act and rules was started in our country, the pharmaceutical industry was in the preliminary stage and most of the formulations and all the bulk drugs were being imported from other countries. Gradually in the industry started development and at present it is full swing.

As the Drugs manufactured and sold in the country play a major role in maintenance of the health of the people of the country, the enforcement of the Act and Rules becomes strieter and stricter day by day. To get a quality product stricter controls during manufacturing is required. The Government was thinking to bring Good Manufacturing Practices as a mandatory provision under the Rules since long. Ours is a democratic set up and so many lengthy procedures are to be followed for making any amendment in the Act and in the Rules. After following different such procedures the Central Govt. Ministry of Health and Family Welfare (Department of Health) Published the draft Rules for including the provisions of Good Manufacturing Practices and the provisions of Maintenance of Records (Manufacturing and Testing) as required under Section 12 and Section 33 of the Drugs and Cosmetics Act. 1940 undser Notification of Govt. of India, The Gazette of India, extraordinary Part-II, Section 3, sub-section (i) dated 22nd June,1987 at the pages 1 to18 inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public.

The copies of the said Gazette were made available to the public on 4th August, 1987.

After considering the objections and suggestions received from the public on the said draft the same were considered by the Central Govt., Thereafter, in exercise of the powers conferred by Section 12 and Section 33 of the said Act, the Central Government after consultation with the Drugs Technical Advisory Board have made certain Rules to further amend the Drugs and Cosmetics Rules 1945, which is known as the Drugs and Cosmetics (Sixth Amendment) Rules, 1988, 1988. It has come in force from the date of the publication of the same in the Official Gazette.

Under this Amendment, Schedule M and Schedule U of the Drugs and Cosmetics Rules, 1945 have been substituted. Schedule M gives details of Good Manufacturing Practices, requirments of premises, plant and equipment and other details while Schedule U gives details about the records to be maintained by a manufacturer.

Schedule M is divided in to two parts. Part-I covers Good Manufacturing Practices under the following sub heads:

(1) Factory Premises.
(2) General requirements.
(3) Sterile products
(4) Working space and storage area
(5) Health, Cleaning and Sanitation of workers.
(6) Medical services.
(7) Sanitation in the Manufacturing premises.
(8) Equipments.
(9) Raw Materials.
(10) Master formula records.
(11) Batch manufacturing records.
(12) Manufacturing operations & controls.
(13) Processing & recovery.
(14) product containers and closures.
(15) Labels and other printed materials.
(16) Distribution records
(17) Records of complaints and adverse ractions.
(18) Quality control system.

While Part-II covers requirements of plant and equipments giving list of equipments and area of the manufacturing sections required for each dosage forms which covers following categories:

(1) Ointments, Emulsions, Lotions and Suspensions.
(2) Syrups, Elixirs and Solutions.
(3) Pills, compressed tablets and hypodermic tablets.
(4) Powders.
(5) Hard Gelatin Capsules.
(6) Surgical dressings other than Absorbent Cotton Wool.
(7) Eye Ointments, Eye Lotions and other preparations for external use.
(8) Pessisaries and Suppositories.
(9) Inhalers and Vitrallae.
(10) Repacking of drugs and pharmaceuticals Chemicals
(11) Parenteral Preparations.

Schedule M also clarifies that the Licensing Authority shall have discretion to examine the suitability and adequcy of the machinery, eqipments and premises for the purpose taking into consideration the requirements of the Licensee. Further, the requirements of Schedule M are subject to the modiciation at the discretion of the Licensing Authority and if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case he is empowered to use his discretion.

Further, Schedule M gives equipments and space requirements for above stated categories of drugs only. There are in addition other categories of drugs such as basic drugs, phar-

maceutical chemicals and aids, medicinal gases, empty gelatin capsules, mechanical contraceptives, new dosage forms, etc. which are not listed in Schedule M. The Licensing Authority should in respect of such categories of drugs use his discretion to examine the adequacy or otherwse of the factory premises, space, plant and machinery and other requisites, having regard to the nature and extent of the manufacturing operations involved and direct the manufacturer to carry out necessary modification in them and on the modifications having been made approve the manufacture of such categories of drugs.

As regards schedule U it covers the maintainance of different types of records such as.

(1) Substances other than Parenteral Preparations in General.

(2) Parenteral Preparations.

(3) Records of raw materials

(4) Analytical Records

(5) Tablets and Capules

(6) Analytical records for Parenteral Preparations including Pyrogen test, Toxicity test.

(7) Analytical records for other drugs.

(8) Analytical records for raw materials.

(9) Analytical records for Containers, Packing Materials, etc

In addition to the above records Schedule U states that the provisions of Schedule U represent the minimum requirements to be complied with by the licensee. The Licensing Authority may, however direct the nature of records to be maintained by the licensee for such products which are not covered by the categories described above.

Further, the Licensing Authority may permit the licensee to maintain records in such a manner as are considered satisfactory provided the basic requirements laid down above are complied with.

The Licensing Authority may at his discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case.

The above is the general break up and information about Schedule M and Schedule U which are now made mandatory for Good Manufacturing Practices. However, the following points requires more stress and they are very important points

General Requirements:

1. Factory Premises:

(a) The premises should be provided with underground drainage system in the processing area as far as possible. The sanitary fitting and electrical fixtures in the manufacturing area should be concealed and ventilation and air inlet point should be flushed with the wall as far as possible.

(b) Water Supply: Water used in the manufacture should be pure and of a drinkable quality free from pathogenic micro-organisms.

2. Sterile Products

(a) For the manufacture of Sterile products separate encloused area specifically designed for the purpose should be provided. This area should be provided with air locks for entry and should be essentially dust free and ventilated with an air supply. For all areas where aseptic manufacture is to be carried out, air supply should be through bacterial retaining filters (HEPA filters) and should be at a pressure higher than in the adjacent area. For performance on installation the filters should be checked periodically and thereafter records thereof should be maintained.

(b) Routine microbial counts of all sterile areas should be carried out during manufacturing operations. The results of such counts should be checked against established house standards and records should be maintained.

(c) Special procedures to be followed for entry and leaving the manufacturing area should be written down and displayed.

3. Health Clothing and Sanitation of Workers:

All the personnel including temporary staff who come into direct contact with the products including raw materials should undergo periodical health check up. Just before entry to the manufacturing area, there should be a change room (minimum 8 sq. metre) separate for each sex with adequate facility for personal cleanliness.

4. Sanitation in the Manufacturing Premises :

(a) The manufacturing area should not be utilised for any other purpose.

(b) A routine sanitation programme should be drawn out and observed, which should be properly recorded and which should indicate specific areas to be cleaned and cleaning intervals and cleaning procedure to be followed including equipment and materials to be used for cleaning and records of compliance in respect of sanitation should be maintained for inspection.

5. Equipment:

(a) Specific written cleaning instructions for all equipment and utensils should be readily available and the operators are required to be familiar with them.

(b) Manufacturing equipment and utensils should be thoroughly cleaned and if necessary sterilized in accordance with the written and specific instructions.

(c) The accuracy and precision of the equipment used for specific filling should be checked and confirmed at regular intervals and records of such checks should be maintained.

(d) The accuracy of premise filling should be checked, confirmed and calibrated at regular intervals and records of such checks should maintained.

(e) Equipment used for sterilization of drugs should be fitted with recording devices so as to monitor and evaluate the performance of the equipment and should be calibrated and checked at regular intervals and records thereof should be maintained.

(f) Equipment used for critical steps in processing should be monitored by devices capable of recording the permanent parameers or with alarm system to indicate mal-functions. These devices should be calibrated and tested and records thereof should be maintained.

6. Raw Materials:

(a) inventory of all the raw materials should be used at any stage of manufacture of drugs and records of the same should be maintained as per Schedule U.

(b) The raw materials should be released from Quarentine by qualified control personnel through written instructions..

(c) The raw materials should be so arranged that all rejected materials are conspicuously identified and destroyed or returned to the suppliers as soon as possible and records are maintained thereof.

7. Master Formula Records:

The licensee should maintain Master Formula Records relating to all manufacturing procedures for each product which should be prepared and endorsed by the competent technical staff i.e. head of Production and Quality Control.

8. Batch Manufacturing Records:

Same should be maintained as per the details given in Schedule U for each categoy.

9. Manufacturing Operations and Controls:

(a) Products not prepared under aspeptic conditions should be free from pathogens like Salmonilla, E. Coli, Pyocyamea, etc.

(b) labels should be attached to all mechanical manufacturing equipment during their operations with conspicuous labels bearing the name of the product, batch no. etc.

(c) Precautions against contamination and mix-up - the Licensee should prevent cross contamination of drugs with sex hormones, corticosterioids, β -lactum antibiotics, antineoplastic drugs by appropriate methods which may include:

(i) Carrying out manufacturing operations in separate building of adequately isolating the operations by tota enclosure within the building;

(ii) Using appropriate pressure differential in the process area;

(iii) Providing a suitable exhaust system and

(iv) Designing laminar flow sterils air systems for sterile products.

(d) Germicidal efficiency of UN lamps should be checke and recorded indicating the buring hours or checked by using intensity meter.

(e) Water for Injection I.P. should either be used immediately or it should be stored to prevent microbial growth a temperature of not less than 80^0C in a jacketted stainless steel storage tank.

(f) Individual containers of liquid orals, parenterls, ophthalmic solutions, etc. should be examined aginst black/while background.

(g) Finished tablets should be inspected for presence of foreign matter besides any other defects.

(h) Expert technical staff approved by the Licensing Authority should check and compare actual yield against theoretical yield before final distribution of the batch.

(i) All process controls as required under master formula including room temperature, relative humidity, weight variation, disintegration time, mixing time, homogenicity of suspensions, volume filled, leakage and clarity should be checked and recorded.

10. Reprocessing and Recovery:

(a) If a product batch has to be reprocessed, reprocessing procedure should be authorised and recorded. An investigation should also be carried out into the cuase necessitating reprocessing and appropriate corrective measures should be taken for prevention of recurrence.

11. Product Containers and Closures:

(a) All containers and closures should comply with the pharmacopoeial requirements.

(b) Whenever bottles are being used, the written schedule of cleaning should be laiddown and followed. Where bottles are not dried after washing, they should be rinsed with deionised water or distilled water.

12. Labels and other Printed Materials:

(a) Prior to issue, all labels for containers, cartons and boxes and all circulars, inserts and leaflets should be examined and released as satisfactory for use by the quality control personnel.

(b) A known number of labelling and packaging unit should be used and if required coded. Such issues should be made against a written signed request which indicates the quantity and the types required.

(c) Prior to packaging and labelling of a given batch of a drug it must be ensured that the batch has been duly tested, approved and released by the quality control personnel.

(d) Records should be maintained for each shipment received on each packaging materials indicating receipt, examination relating to testing and whether accepted or rejected.

13. Distribution Records:

Records for distribution of drugs should be maintained for distribution of finished batch of a drug in order to facilitate prompt and complete recall of the batch, if necessary.

14. Records of Complaints and Adverse reactions:

Records of serious adverse reactions resulting from the use of drug alongwith the comments should be informed to the concerned Licensing Authority.

15. Quality Control System:

Every manufacturing establishment should have a quality control department supervised by approved expert staff directly responsible to the management but independent of other departments. The quality Control department shall control all the raw materials, monitor all in process quality checks and control the quality and stability of finished products.

The quality control department should have the following principal duties:

(i) to prepare detailed instructions, a writing for carrying out each test and analysis;

(ii) to release or reject each batch of raw materials;

(iii) to release or reject each batch of finished products i.e. ready for distribution.

(iv) to evaluate the adequacy of the conditions under which raw materials semi finished products and finished products are stored;

(v) to evaluate the quality and stability of finished products and, when necessary of raw materials and semi-finished products.

(vi) to establish shelf life and storage requirements on the basis of stability tests related to storage conditions;

(vii) to examine returned products as to whether such products should be released,reprocessed or destroyed.

So, the above are the important points which the manufacturers have to keep in mind while following Good Manufacturing Practices.

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- with 0.9% Sodium Chloride Injection I.P.
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Antipsychotic Agents (Neuroleptics) In Medicine And Pharmacy

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Institute of History of Medicine and Medical Research,
Hamdard Nagar, New Delhi-110 062.

The antipsychotic agents, now more commonly called the "neuroleptics" are one of the most important and widely used class of drugs which developed after the second world war. In the course of these years their use has rather increased instead of getting limited. The drug effect that we now attribute to this class of drugs has certainly revolutionized the institutional practice of psychiatry and perhaps psychiatry in general. These were shown to be different from sedatives as early as in 1951. Their pharmacological character was described by Charpentier in 1950 although these had been synthesized many years earlier. Their use in psychiatry was made for the first time by Delay and Deniker in 1952. Since then the therapeutic applications of these drugs have increased and the drugs have acquired some specificity towards their usefulness. Although the phenothiazines were the first ones to be introduced, these were soon followed by the more potent butyrophenones and many others, all of whom have a fairly common mechanism of action. However, in recent years atypical neuroleptics have developed and some of which have been found to be causing fewer side effects.

In actual practice of medicine besides drug therapy social and psychological treatments are also employed for better results. Social treatment involves attention being paid to the patient's environment and social functioning. Patients with any degree of residual impairment and negative symptoms usually require rehabilitation in a structured work and social environment. Some patients can manage a normal job while others require a sheltered workshop. Psychological treatment consists of reassurance, support and a good doctor patient relationship. Psychotherapy of an intensive or exploratory kind is contraindicated.

Classification And Chemistry of Neuroleptics (Fig.1)

The neuroleptics fall mainly into three clinical groups namely

(A) PHENOTHIAZINES AND RELATED TRICYCLIC COMPOUNDS :

They form the most import group comprising of :

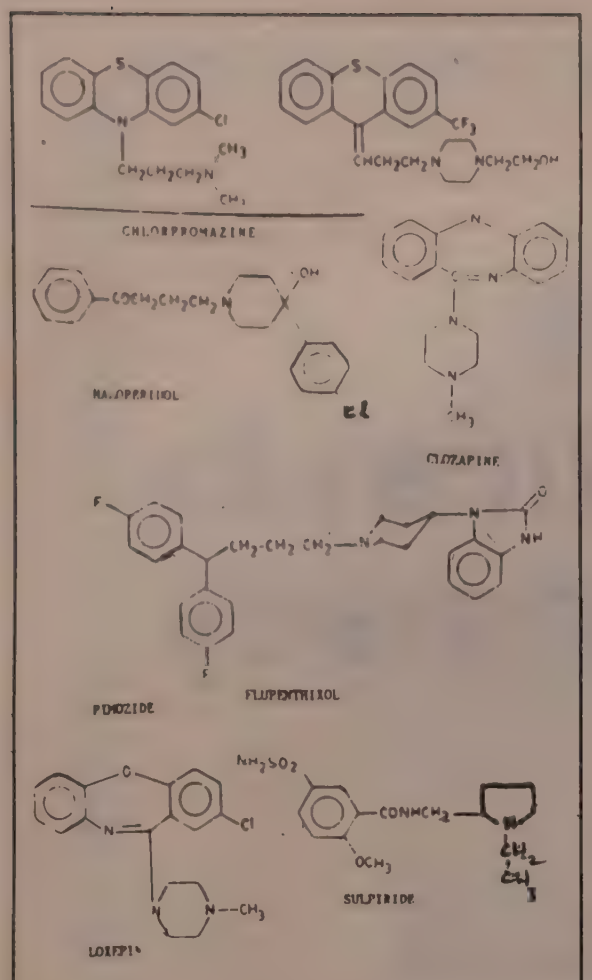
a. Phenothiazines

i. Aliphatic derivatives (e.g. Chlorpromazine, trifluopromazine and promazine).

ii. Piperazine derivatives (e.g. Fluphenazine, perphenazine and butaperazine).

iii. Piperidine derivatives (e.g. Thioridazine, mesoridazine and piperacetazine).

The nature of side chain determines both the potency and the pharmacological specificity. Thus piperazine compounds are more potent than aliphatic compounds and have relatively less adrenoceptor blocking activity, while piperidine group is intermediate in potency and possess more antimuscarinic activity than chlorpromazine.



Structure Of Some Clinically Useful Neuroleptics.

b. Thioxanthenes (e.g. Flupenthixol, Chlorprothixene, chlopenthixol and thiothixene)

They differ from phenothiazines only in the substitution of carbon for 'N' in the middle ring position. Flupenthixol is identical with fluphenazine apart from this change.

c. Dibenzodiazepines (e.g. clozapine)

The middle ring is a seven membered structure similar to those of benzodiazepines.

B. BUTYROPHENONES (e.g. Haloperidol, benperidol, bromperidol, oxiperomide and trifluoperidol)

Butyrophenones are chemically unrelated to phenothiazines and were accidentally discovered in the course of screening a variety of compounds related to the analgestic pethidine.

C. BENZAMIDES (e.g. Sulpiride)

Originated from the modification of structure of procainamide. This first led to metoclopramide, a drug which reduces gastrointestinal motility and also has antidopamine effect in the periphery as well as showing some antipsychotic activity.

D. DIPHENYLBUTYLPIPERIDINE DERIVATIVES (e.g. Pimozide, penfluridol, fluspirilene and chlopimozide)

The only major advancement over the introduction of these four classical classes has been the subsequent development of depot preparations. For example, fluphenazine decanoate, haloperidol decanoate and flupenthixol decanoate have been used widely in the maintenance therapy of schizophrenia (Johnson, 1984).

MECHANISM OF ACTION

There are five identified dopamine pathways in the brain, each accounting for an effect of neuroleptics. The mesolimbic pathway is most probably involved in the antipsychotic efficacy of neuroleptics. The nigrostriatal pathway is implicated in extrapyramidal side effects. The mescocortical pathway is probably involved in sedative action and hypothalamic-hypophyseal and incertohypothalamic pathways are responsible for the neuroendocrine side effects caused by neuroleptics (Fig.2).

Neuroleptics selectively block the D_2 type of dopamine receptors in brain and pituitary. There are at least two types of dopamine receptors (Table-1).

Table 1 : Dopamine Receptor Types (Kebabian and Calne, 1979; Gildberg and Kohli, 1983).

	D_1	D_2
EFFECTS	Activation of adenylate cyclase	No activation of adenylate cyclase
	Vasodilatation	Inhibition of transmitter release
	Increased force of contraction of myocardium	Central actions
AGONISTS		
Dopamine	+ (u molar)	+(nm)
Apomorphine	± PA* (um)	+ (nm)
Bromocriptine	± PA*(um)	+(nm)
ANTAGONISTS		
Phenothiazines	+ (um)	+(nm)
Butyrophenones	+ (um)	+(nm)
Sulpiride	Weak	Potent
Domperidone	–	+(nm)

*PA - Partial agonist.

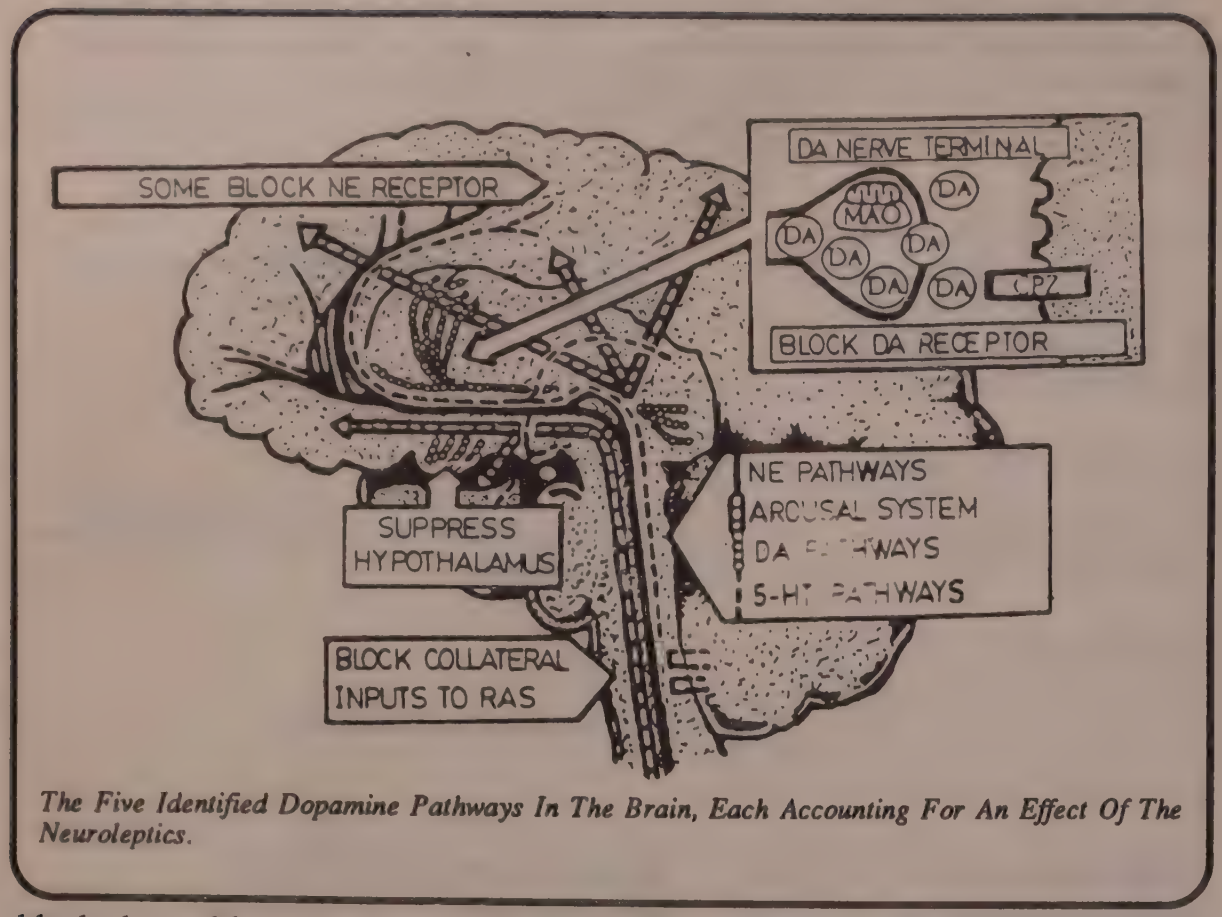
The D_1 receptor is defined as that which stimulates the formation of cyclic AMP (cAMP). Since the D_1 receptors can be blocked only by high (i.e., micromolar) concentrations of neuroleptics, they are not blocked at ordinary doses that patients take. The D_2 type, on the other hand, is defined as that dopamine receptor which is sensitive to nanomolar concentrations of neuroleptics. There are important clinical implications to the fact that the D_2 receptor exists in two states: a high-affinity state (termed D_2 high) which is very sensitive to nM dopamine; and a low-affinity state which is only affected by uM dopamine. Both states are readily blocked by nM concentrations of neuroleptics (Fig.3). The D_2 receptor interferes with the synthesis of cAMP in both brain and pituitary. The D_2 receptor hyperpolarizes the cell. There is as yet no known functional correlate for the D_1 receptor site.

. The conventional view that defines the mechanism of action of neuroleptics as related to their ability to acutely block the dopamine receptors fails to account for the delay in clinical efficacy that is observed. Almost 3 weeks or more are required to produce amelioration of psychotic symptoms but blockade of dopamine receptor is an immediate biochemical effect. Hence, a look beyond the acute action of neuroleptic is essential and examine the compensatory adjustments that occur with chronic use (Fig. 2,3). The immediate action of neuroleptic is to block both pre and post synaptic dopamine receptors. Blockade of presynaptic dopamine receptors initiates a short term compensatory adjustment resulting in increased dopamine turnover. This is also related in part to multineuronal feedback mechanism stimulated by the lack of postsynaptic cell activity. Thus these short term measures largely offset the blocking action of neuroleptics.

After 2 to 3 weeks of treatment, long term adaptations begins to supplant the short term compensations by way of postsynaptic receptors supersensitivity which then helps to offset the blocking action of neuroleptics. Also, the presynaptic receptors become supersensitive overcoming the presynaptic

Table 2: Neuroleptics Of Choice For Various Conditions (Black et al, 1985)

Condition	Recommended Drug
PSYCHIATRIC	
Agitation And Psychosis	Chlorpromazine, thioridazine
Withdrawal and psychosis	Fluphenazine, haloperidol, trifluoperazine
Tendency for severe parkinsonism or acute dystonia	Chlorpromazine, thioridazine
Tendency for akathisia	Chlorpromazine, thioridazine
OPTHTHALMOLOGIC	
Accommodation difficulties	Fluphenazine, haloperidol, prochlorperazine trifluoperazine
ALLERGIES	
	Chlorpromazine, thioridazine
PULMONARY	
Chronic obstructive pulmonary disease	Haloperidol, prochlorperazine, trifluoperazine.
CARDIOVASCULAR	
Coronary artery disease	Fluphenazine, haloperidol, trifluoperazine
Hypertension treated with prazosin	Fluphenazine, trifluoperazine
Arrhythmia	Avoid thioridazine
GASTROINTESTINAL	
Nausea and vomiting	Any neuroleptic except thioridazine,
Diarrhoea	Chlopromazine
UROLOGIC	
Urinary Retention	Fluphenazine,haloperidol,prochlorperazine, trifluoperazine
ENDOCRINOLOGIC	
Galactorrhea, Menstrual irregularly caused by use of neuroleptic,breast cancer	Switch to chlorpromazine, thioridazine
NEUROLOGIC	
Parkingson's disease	Chlorpromazine, thioridazine
DEMENTIA WITH BEHAVIORAL DISORGANIZATION.	Fluphenazine, haloperidol, trifluoperazine.



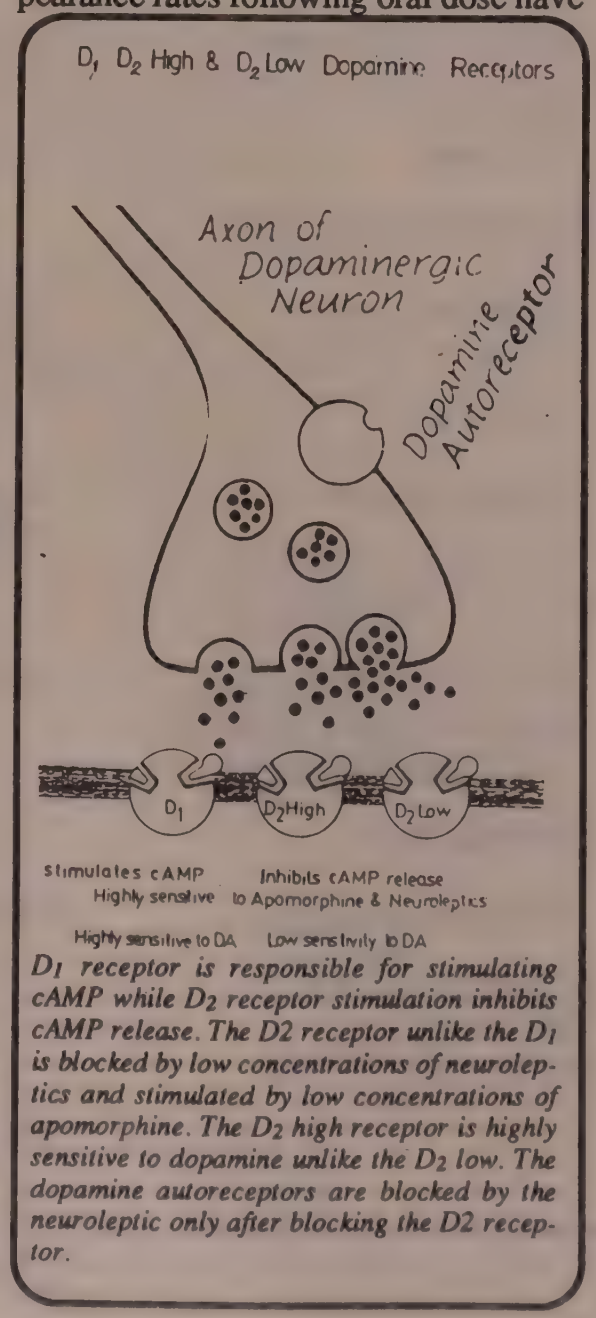
The Five Identified Dopamine Pathways In The Brain, Each Accounting For An Effect Of The Neuroleptics.

blockade, and hence helps to bring the dopamine turnover rate back to normal levels. The ultimate action after 2 to 3 weeks is a reduction in transmitter binding to the post synaptic receptor while short term compensations undergo tolerance.

PHARMACOKINETIC CONSIDERATIONS

METABOLISM AND BIOTRANSOFRMATION OF NEUROLEPTICS

A. *Chlorpromazine :* Of all neuroleptics, the metabolism of Chlorpromazine have been extensively studied. Over 160 metabolites of Chlorpromazine have been postulated, of which some have been identified and fewer tested for pharmacological activity. The routes of metabolism of chlorpromazine involve nuclear transformations of the tricyclic portions (hydroxylations with subsquent conjugation as well as sulfoxidation) and transformations of the aliphatic side chain (demethylation, N-oxidation and deamination). Of the various metabilites, 7-hydroxy derivative has attracted maximum interest and is associated with clinical improvement. (Phillipson etal, 1977). Kinetic studies revealed that oral absorption of Chlorpromazine can be highly erratic. The absorptive half life has been calculated to be 1.5 hours. Plasma disappearance rates following oral dose have shown a biexponential curve characterisitic of highly lipid soluble drugs. Variability in the oral absorption is not due to poor absorption from the gut lumen or first pass metabolism in the liver but because of large and variable amount of tissue binding and their high lipid solubility. Protein binding is relatively high (98 to 99%) and volume of distribution rather large (7 L/Kg.).



D_1 receptor is responsible for stimulating cAMP while D_2 receptor stimulation inhibits cAMP release. The D2 receptor unlike the D_1 is blocked by low concentrations of neuroleptics and stimulated by low concentrations of apomorphine. The D_2 high receptor is highly sensitive to dopamine unlike the D_2 low. The dopamine autoreceptors are blocked by the neuroleptic only after blocking the D2 receptor.

B. *Thioridazine :* Thioridazine undeergoes a ring sulfoxidation producing inactive metabolites. The thiomethyl ring substituent undergoes two sulfoxidations, sulfoxide (One Oxygen) and sulfone (Two Oxygen), both are active. The side chain sulfoxide (mesoridazine) and sulfone (Sulforidazine) metabolities have themselves been used an antipsychotics. For this reason the kinetic study and relationsjip of plasma concentration to clinical efficacy is difficult. Aso the three active substances have different plasma half lives i.e. thiroidazine 2 hours, mesoridazine 16 hours and sulforidazine 13 hours.

C. *Haloperidol :* Metabolism of haloperidol involves N-dealkylation, oxidation and conjugation. The kinetics of haloperidol in man have been studied with a specific Gas Liquid Chromatography (GLC) method. Serum half life ranged between 10-19 hours after intravenous administration and 12-38 hours after oral administration. Bioavailability is of the order of 60 percent. Protein binding was found to be 92 percent (Forsman and ohman, 1979).

DEPOT NEUROLEPTICS

A depot neuroleptic has been arbitrarily defined as a neuroleptic which can be administered in such a way that after a single dose, therapeutically efficient tissue concentration of at least one week's duration is achieved. After the injection the ideal depot preparation should pharmacokinetically cause the active substance to be released at a constant, slow speed so that the maximum/minimum plasma level fluctuations in the depot interval is kept at a minimum and to use a depot interval of a suitable duration (2-4 weeks). More than 90% of released neuroleptic is

bound to plasma proteins and unbound either passes the blood brain barrier or is distributed in the tissues where metabolism takes place.

STEADY STATE PLASMA CONCENTRATION AND THERAPEUTIC EFFECT:

The problems of relating steady state plasma concentration of neuroleptics to therapeutic effect in schizophrenia have been discussed by Grahme-Smith and Orr (1978). One of the problems is the heterogeneity of the schizophrenic syndrome. Some patients will not respond to drugs whatever the plasma concentration may be. Others may improve irrespective of medication. Also within the same group, some symptoms may respond to drugs but not others and improvement may be related to the formation of active metabolite rather than to the effect or parent drug. In general it apears that best response to neuroleptics drugs occurs in patients with acute schizophrenic episodes and positive symptoms. In these patients there is probably an optimal therapeutic range of neuroleptic drug concentration.

DRUG MONITORING :

A number of methods have been developed for determination of plasma levels of neuroleptics. These methods are GLC, high performance liquid chromatography (HPLC), radioimmunoassay (RIA) and most recently radioreceptor assays (RRA) (Creese and Snyder, 1977; Javaid et al, 1983). recently, it has been concluded that plasma drug level monitoring may be useful in treatment with chlorpromazine, flupenazine, haloperidol, perphenazine, thiothixene & sulpiride (Morselli, 1981)

ADVERSE DRUG REACTIONS

1. EXTRAPYRAMIDAL SYNDROME (EPS):

It is usually dose related and takes three forms.

a. Pseudoparkinsonism (4-40%) : The symptoms may include mask like face, drooling, temors, pillrolling motion and rigidity. The symptoms are easily controlled with antichloinergics. It has been suggested that parkinsonism results from drug induced deplorisation blockade in A_9 dopaminergic neurones in the substantia nigra and increased cholinergic activity in the corpus striatum which in turn increases the release of GABA.

b. Dystonias (2-10%) : Consists of neck muscle spasms, extensor rigidity of back muscles, aching and numbness of limbs.

c. Akathisia (7-10%) : It is one of the most common motor side effect. Amitryptiline in the dose of 100 mg/d produces a dramatic improvement of akathisia. Several other drugs used are benzodiazepines, anticholinergics, amantadine and clonidine.

2. TARDIVE DYSKINESIA :

It is a delayed adverse effect which appears months or sometimes several years after the start of neuroleptic drug treatment. The clinical features consists of bizarre movements involving oral, lingual, buccal, facial, trunk or limb muscles. The incidence is probably 10-20% in patients receiving neuroleptics for over a year. the underlying mechanism is not clear. It may be due to the development of D_2 receptor supersensitivity in the corpus striatum which has been demonstrated in rats after long term treatment with neuroleptic that cuase tardive dyskinesia in man.

Treatment of tardive dyskinesia involves :

a. Use only the minimum effective dose.

b. Alteration of neuroleptic medication (putting off dose may produce transient improvement but ultimately may worsen the situation).

c. Depletion of dopamine stores by reserpine or tetrabenazine though it may lead to mental depression.

d. Increasing cholinergic activity by withdrawing any anti cholinergic drug being given against EPS. Another approach is to administer L-dopa that will desensitize the dopamine receptor and cause the striatal neurons to slow down the synthesis and reduce the number of dopamine receptors. Precurssors of acetycholine (deanol, choline) are marginally effective.

e. Increasing GABA inhibitory action by using benzodiazepines. There is complex interrelation of GABA with dopaminergic/cholinergic balance.

f. Lithium, valproate or baclofen are also found beneficial.

g. Substitution of more selective atypical neuroleptics which spare the nigrostriatal system may be a practical alternative.

However, the most rewarding approach may be by 'drug holidays' say one month in six, though there is risk of therapeutic relapse.

3. NEUROLEPTIC MALIGNANT SYNDROME :

This is a rare idiosyncratic response which has been observed after treatment with phenothiazines and butyrophenones. It is characterised by akinesia, muscle rigidity, hyperthermia, autonomic instability and altered consciousness. It is possibly caused by dopamine receptor blockade in the basal ganglia.

4. NEUROENDOCRINE EFFECTS :

The serum concentrations of prolactin are increased after administration of neuroleptics. The dopamine releasing neurone i.e. arcuate nucleus releases dopamine from hypothalamus via the hypophyseal portal blood vessels to pituitary and inhibits the release of prolactin from mamotroph cells. Under the influence of neuroleptics, the mamotroph dopamine receptor are blocked resulting in hyperprolactaenemia. Other effects include amenorrhoea, galactorrhoea, mastalgia and gynecomastia in males in large doses.

5. CARDIOVASCULAR EFFECTS :

The commonest cardiovascular effect of phenothiazines is postural hypotension due to peripheral and central alpha-adrenoceptor blockade. This is combined with a reflex tachycardia and peripheral vasodilatation which

can lead to hypothermia. Phenothiazines also exert quinidine like anti-arrhythmic and cardiodepressant effect. Butyrophenones and thioxanthenes also have alpha-adrenoceptor blocking effect but these are absent with atypical neuroleptics.

6. ANTICHLINERGIC EFFECTS :

The muscarinic blockade may cause dryness of mouth, nasal congestion, constipation and blurred vision etc.

7. SEDATION AND DEPRESSION :

Sedation and depression may occur with phenothiazines and butyrophenones.

8. HYPERSENSITIVITY REACTIONS :

Jaundice due to intrahaepatic cholestasis occurs in 2-4% of patients treated with chlorpromazine which is hypersensitivity reaction and is associated with eosinophilia.

9. OCULODERMAL MELANOSIS :

Long term administration of high doses of chlorpromazine may cause pigmentary changes in the skin and eyes termed as oculodermal melanosis.

10. HEMATOLOGIC :

Eosinophilia, leucopenia, leucocytosis, anaemia, aplastic anaemia, hemolytic anaemia, thrombocytopenia etc.

11. AGRANULOCYTOSIS :

Most cases occur between 4-10 weeks of therapy.

12. EPILEPTOGENIC EFFECTS (0.5-1%) :

They are increased with more sedative agents i.e. aliphatic phenthiazines thioxanthenes-Butyrophenones Piperidines Piperazines.

13. HEAT STROKE/HYPERPYREXIA :

Induced by neuroleptics is reported. They may act in several ways including disrupting the hypothalmic thermoregulatory centre, adrenergic blockade and by autonomic mechanisms.

14. RESPIRATORY :

Laryngospasm, bronchospasm, dyspnoea.

15. SUDDEN DEATH :

Occasionally reported. Previous brain damage or seizure may be predisposing factors, avoid high doses in known seizure patients.

DRUG INTERACTIONS :

1. BARBITURATES, NARCOTIC ANALGESICS, ANAESTHETICS, PROCARBAZINE AND ALCOHOL: Use cautiously because of additive CNS depressant effects.

2. ANTICHOLINERGICS : There may be additive anticholinergic effect or decreased antipsychotic efficacy.

3. TRICYCLIC ANTIDEPRESSANTS (TCA) : Neuroleptics may inhibit the hepatic metabolism of certain TCA e.g. imipramine, nortryptyline, clinical effects are difficult to predict (Gram & Overo, 1972).

4. METYROSINE : When administered with phenothiazines or haloperidol, EPS may be potentiated by inhibiting catecholamine synthesis.

5. LEVODOPA : Efficacy may be reduced by concurrent administration of neuroleptics as phenothiazines can cause parkinsonium in their own right.

6. QUINIDINE : Concomitant administration with pehnothiazines may result in additive cardiac depressant effects.

7. ANTIDIARRHOEAL MIXTURES AND ANTACIDS : May reduce phenothiazine absorption.

8. ANTIHYPERTENSIVES : The neuroleptics may abolish the antihypertensive action of guanethidine by inhibition of neuronal uptake. Phenothiazines may enhance the hypotensive effect of nitrates.

9. PROPRANOLOL/ METOPROLOL : Concomitant administration may result in increased plasma levels of both drugs.

10. LITHIUM : It may lower plasma levels of Chlorpromazine and cause severe neurotoxicity when combined with thioridazine and other phenothiazines. Haloperidol combined with lithium has also produced a severe neurotoxicity (extrapyramidal, neuroleptic maligant syndrome) that may be permanent. Both these interactions appear to be rare. Lithium and phenothiazines are individually liable to induce hyperglycemia (king, 1978) but combination lack the effect.

11. EPINEPHRINE : Should not be used because phenothiazines block adrenergic receptors permitting unopposed beta activity (vasodilatation, high heart rate) to predominate.

12. METHYLDOPA : Concomitant administration of haloperidol and methyldopa may produce psychiatric symptoms (i.e disorientation, irritability, aggressiveness and assaultiveness).

13. PHENYTOIN SODIUM : Phenothiazines may interfere with phenytoin metabolism and induce pheytoin toxicity via altered hepatic metabolism, although opposite effect has been seen with thioridazine.

14. POLYPEPTIDE ANTIBIOTICS : Phenothiazines may exacerbate neuromuscular respiratory depression.

15. METRIZAMIDE : Phenothiazine may predispose patients to metrizamide induced seizures.

16. CORTICOSTEROIDS : Chlorpromazine reduces gut motility and may enhance the absorption of corticosteroids.

17. DIGOXIN :

Chlorpromazine reduces gut motility and may enhance the absorption of digoxin.

18. MEPERIDINE : A marked, debilitating lethargy was observed in normal subjects when given in combination with chlorpromazine. Systolic and diastrolic blood pressures were depressed due to alteration of meperidine metabolism by chlorpromazine.

19. ORAL ANTICOAGULANTS : Due to the inhibition of liver microsomal enzymes by phenothiazines, the metabolism of oral anticoagulants is reduced resulting in increased activity.

20. LIQUID FOOD (e.g. COFFEE, FRUIT JUICES, MILK, TEA) : Phenothiazines may be precipitated by many fruit juices, milk, tea & coffee which do not redissolve in hydrochloric acid and so might be expected to be only poorly absorbed in vivo. Thus coffee or tea may antagonise antipsychotic efficacy.

21. DRUG (HEPARIN & PENICILLIN) IN SOLUTION : Heparin & Penicillin are precipitated and inactivated if phenothiazine is added to the solution.

22. ORAL CONTRACEPTIVES : Oestrogen containing oral contraceptives may potentiate Phenothazine stimulated prolactin secretion resulting in mammary hypertrophy and galactorrhoea.

23. SKELETAL MUSCLE RELAXANTS : Phenothiazines lower serum and erythrocyte cholinesterase levels causing prolonged d-tubocurarine induced muscle relaxation.

24. MONOAMINE OXIDASE INHIBITORS : The combination may lead to hypertension and increased extrapyramidal reactions possibly because of inhibited metabolism of phenothiazines.

CONTRAINDICATIONS

1. Comatose or severly depressed state, hypersensitivity (cross sensitivity between phenothiazines may occur).

2. Presence of large central nervous system depressants.

3. Bone marrow depression.

4. Blood dyscrasias.

5. Circulatory collapse.

6. Subcortical brain damage.

7. Parkinson's disease.

8. Liver damage.

9. Cerebral arteriosclerosis.

10. Coronary disease.

11. Severe hypotension or hypertension.

NEW USES FOR OLDER DRUGS :

CALCIUM ANTAGONISTS : It has been reported that verapamil is effective in acutely manic patients. Other calcium an tagonist e.g. nifedipine may also have antimanic properties. Recently measurable levels of verapamil and its primary metabolite, norverapamil were observed in the cerebrospinal fluid of schizophrenic patients (steven et al, 1986).

CARBAMAZEPINE : Carbamazepine combined with haloperidol has shown to require lesser amoung of neuroleptic and anticholinergic and produced fewer side effects as compared to the patients on placebo. The mechanism by which carbamazepine exerts its adjunctive effect is not clear. Some argue the psychotropic action of carbamazepine while other relate it to the facilitation of GABA. The lesser incidence of side effect with the combination therapy may be related to the reduced haloperidol plasma levels (Dose et al, 1987).

PROPRANOLOL : The beneficial effects of propranolol in schizophrenia has been reported in its conventional racemic (dl) form. Interestingly, d-propranolol has no known effects on dopaminergic or 5HT system. Possibly it has sustained or stabilised the haloperidol action observed during first week of treatment. Thus it remains a question whether or not propranolol can be modified to produce a more effective anti psychotic agent and provides a challenge to the pharmaceutical industry (Manchanda and Hirsch, 1986).

ANTIDEPRESSANTS : They have been used in schizophrenic patients who show concomitant depression. A recent revival of interest in high dose of diazepam is difficult to explain after the disappointing earlier experience in schizophrenics. Additionally, one puts the patients at risk for development of physical dependence.

TRH : Though thyrotropin releasing hormone (TRH) has little beneficial effect in schizophrenia, favourable report still containue to appear. The activity could be attributed to a major metabolite of TRH which seems to have antidopaminergic action.

OPIOD ANTAGONISTS AND ENDORPHINS : Endorph was found to produce dramatic improvement in psychotic symptoms and its mechanism of action was postulated that some dopaminergic systems in the brain may be involved (Van ree et al, 1985).

ATYPICAL NEUROLEPTICS :

The first commonly recognized "atypical" antipsychotic was the dibenzo-diazepine, clozapine, which was found to be an effective antipsychotic without inducing concomitant extrapyramidal side effects. Unfortunately, clinical use of clozapine was subsequently curtailed by incidence of blood dyscrasias, and especially agranulocytosis, a potentially lethal non-neurological disorder. However, it firmly established that antipsychotic efficacy could be dissociated from the extrapyramidal system, and has provided an invaluable research tool for experimentation in animals. Clozapine has a multiplicy of receptor interactions (including muscarinic, alpha-noradrenergic and histaminergic receptors), although it is unclear whether any specific combination of these may contribute to its unique properties.

The agent most similar to clozapine from both a structural and biological point of view thus far developed is fluperlapine. A comparison of the biochemical and behaviral activity of the two agents revealed that while fluperlapine displays weaker D_2 antagonism in the striatum, thus suggesting it should have a lower propensity to cause EPS, fluperlapine showed greater activity in reversing apomorphine and amphetamine induced stereotypies, generally considered to be striatally mediated.

This structural class, then, seems to hold great promise for the treatment of schizophrenia, provided some difficult toxicity problems can be solved. The most recently developed of the new putative atypical agents is tiospirone. The discovery of this drug, which modeled after clozapine, and the structure activity relationships (SAR) of related compounds have been described. Tiospirone has been shown to be a potent depamine D_2 antagonist, in vitro and in vivo, with little potential to induce catalepsy in rodents, suggesting an atypical profile.

A study in monkeys treated with fluphenazine to induce symptoms of tardive dyskinesia showed that both tiospirone and BMY-13, 980 reduced or abolished the tardive dyskinesia symptoms and induced EPS-like behaviors, in contrast to clozapine and thioridazine, which had no effect. The selective activity of clozapine against D_2 receptors in limbic areas has inspired the development of another new agent, cipazoxapine, which has fared well in the clinic. BMY-14,802, is another example of a pulative atypical agent which does not directly block D_2 receptors.

Table 3: List Of Neuroleptics Available In USA, UK & India

Neuroleptics	USA	UK	INDIA
Chlorpromazine	Promachlor Thorazine	Largactil Chloractil	Largactil
Haloperidol	–	Haldol	Larenase Halopidol Serenace
Fluphenazine	Permitil Prolixin	Modecate Modeten	Anatensol
Trifluoperazine	–	Stelabid Stelazine	Eskazine
Pimozide	–	Orap	Orap Neurap
Thioridazine	Mellaril	Melleril	Mellaril Mellerrets
Prochlorperazine	Compazine	Stemetil	Stemetil
Trifluoperidol	–	–	Triperidol
Fluopromazine	Vesprin	–	–
Methotrimeprazine	Levomepromazine	–	–
Pipercetazine	Quide	–	–
Acetophenazine	Tindal	–	–

Finally, intriguing results recently reported for a nevel 5-HT antagonist, odanserin, suggest that such agents may also be putative atypical antipsychotics which do not exhibit direct dopamine receptor blockade./ Besides these, benzopyrones which include bioflavonoids (e.g. rutin) and coumarin and its derivatives have been tried in chronic schizophrenic disease successfully (Casely-Smith, et al, 1986). Rimcazole, anovel neuroleptic, is devoid of any EPS as judged by its profile in animal behavioural models and by results of early clinical trials in acute schizophrenic patients.

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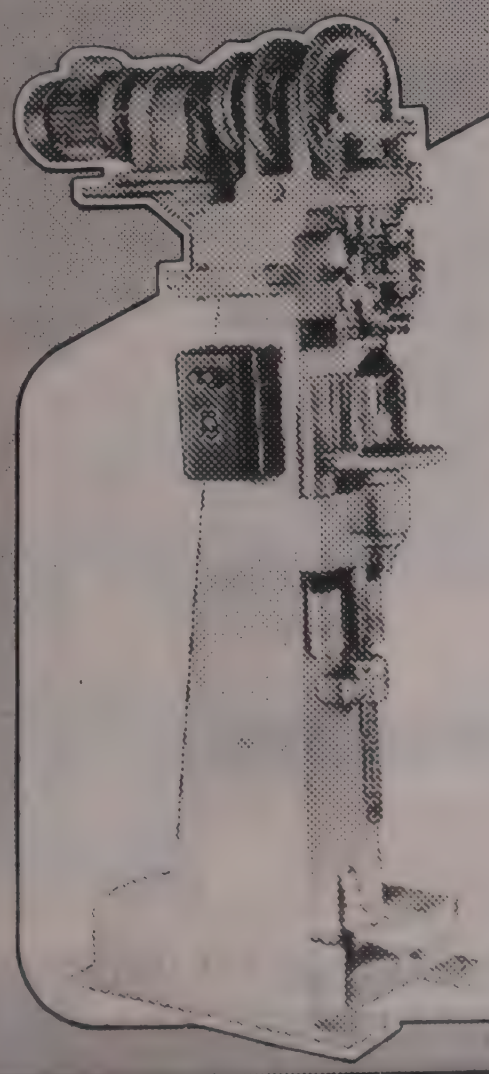

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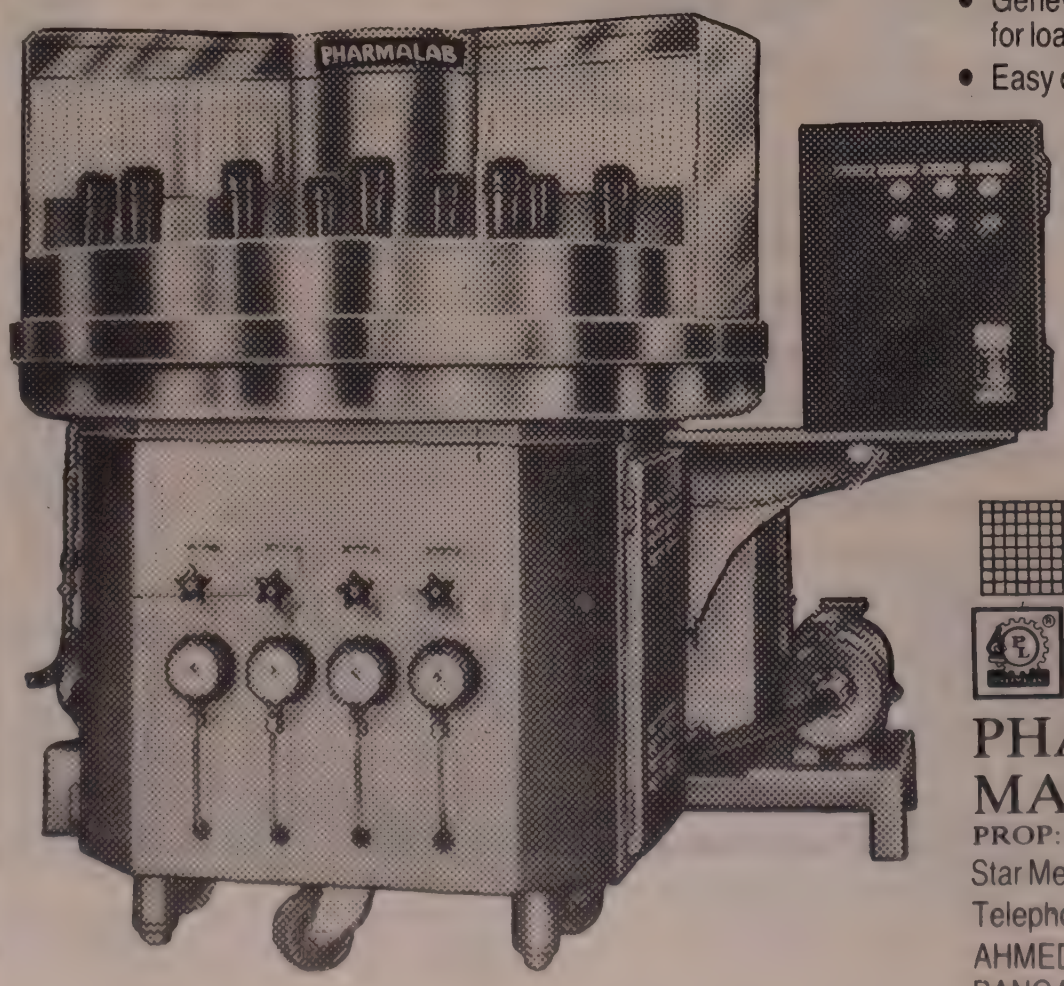

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Trends In Oral Sustained Release Formulations - I

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In the past decade great interest got generated on replacing conventional administration of drugs by delivery systems which would release effective quantities from a protected supply at a controlled rate over a long period of time. Ideally a drug to provide desired therapeutic action should arrive rapidly at the site of action (receptor) in optimum concentration, remain there for desired time, spare other sites and get removed from the site. one of the more recent and interesting results of pharmaceutical research is the fact that absorption rate of a drug can be decreased by reducing its rate of release from the dosage form. The products so formulated are designated as sustained action, sustained release, prolonged action, depot, repository, retarded release, delayed action and timed release medication.[1] These products in most cases are similar in appearance.

Products that have been formulated for the purpose of prolonging absorption include oral, parenteral, topical and implants dosage forms both for human and veterinary use. Oral sustained release products have gained importance because of the technological advances which help achieve zero order release rate of the therapeutic substances.[2] It is not possible to obtain an ideal sustained effect when the drug is given orally because the rate processes are influenced grossly by a number of gastrointestinal tract factors e.g. variation in pH, motility, nature of food, fluid volume and contents, health and disease and in vivo dissolution rate and consequent bio-availability of the drug.

Generally the pharmacokinetics of a drug is controlled by its chemical nature. However decreasing the absorption rate by physical means is a useful method to sustain the drug action when it is not feasible to modify the drug compound at its molecular level. In practice a sustained release formulation is prepared by incorporation of an initial dose portion containing sufficient drug to attain the desired concentration at the receptor site and a sustaining portion containing sufficient drug to maintain this concentration for approximately 10 to 12 hours. Although the action time curve of this formulation is less ideal than the theoretically optimum effect-time curve to be achieved by a sustained action dosage form, it may be emphasized that the difference is caused more by the route of administration (oral) than by the dosage form.

Advantages:

The advantages generally claimed for sustained release products include

1. Improved Therapy:

a) The dosage form provides uniform drug availability/blood levels unlike peak and valley pattern obtained by intermittant administration.

b) The incidence and intensity of undesirable side effects caused by excessively high peak drug concentration resulting from the administration of conventional dosage forms is reduced.

c) It is seldom that a dose is missed because of non-compliance by the patient.

2. Patient Convenience:

Frequency of administration is reduced and thus disturbance to the patient is less particularly at night (resting time).

3. Economy:

a) Sometimes sustained release formulations are less expensive than conventional dosage forms.

b) Economy may also be effected due to decreased cost of nursing time for administration of drugs.

Disadvantages

However, sustained release products are not altogether free from disadvantages some of which are as follows:

1. Usually the amount of drug in a S.R. dosage from is 3-4 times and if a dosage form is used improperly e.g. by chewing instead of swallowing, the patient would receive an over dose. Hence only such drugs which possess a substantial margin of safety can be presented in S.R. form.

2. Improper formulation may result in excessive dosage or the drug release may not be complete[3]

3. In case of accidental failure of the product effective antidote may be difficult to employ.

4. S.R. dosage forms are sometimes costlier because of the technology involved in producing the formulation.

5. S.R. medication should not be used with persons known to have impaired or erratic gastrointestinal absorption or kidney troubles.

6. Drugs having long biological half life are not suitable for presentation in S.R. forms e.g. digitoxin.

7. There is little control in the hands of the physician so far as dose variation is concerned.

8. It is difficult to formulate an ideal sustained release dosage form.

Inspite of the innumerable problems encountered in formulation of oral sustained release dosage forms, a large number of products have been prepared and are being marketed as S.R. tablets, capsules, suspensions etc.

Theory Of Sustained Release:

Sustained action curve is possible only when the drug from the dosage form is supplied for absorption into the blood, at a constant rate equal to the rate constant for the elimination of the drug[1] from the blood times the amount desired to be kept in the blood, Mathematically this relationship is given as

$$K_2B = R = KdG$$

Where

K_2 = rate constant for elimination of drug from blood

B = quantity of drug to be maintained in blood

R = replacement rate

Kd = constant relating the amount that can be absorbed under standard volumean concentration conditions.

G = quantity of drug that the dosage from must supply (maintain) in the depot.

When only a fraction, f, of the drug is available because of irreversible binding or degradation, the amount available for absorption must be increased by 1/f. The value for B is usually known or can be ascertained if the drug and its effect can be measured. It is often possible to obtain a value for K_2 by plotting a log of the concentration of the drug remaining in blood versus time. The negative slope of the resulting straight line is assumed to be the elimination rate constant for design purposes.

When the initial dose (Dn) is estimated from multiple dose data, the dose (Dn) is the quantity needed to produce B (quantity of drug that must be maintained at receptor site). The correction for irreversible binding and/or degradation of the drug in depot(1/f) is not required when Dn is obtained from multiple dose data. Ideally, knowledge of the absorption rate constant K_1, the elimination rate constant (K_2) and the distributive rate constants (K_{12} K_{21}) should enable the formulation scientist to construct a curve similar to that given for a single dose. Number of methods for determining absorption rate constants have been reported[4,5]

The total dose[6] of drug, Dt, in a prolonged action preparation comprises of the normal dose, Dn, and the sustaining dose Ds i.e.

$$Dt = Dn + Ds$$

In the first order elimination, rate constant is K, the rate at which the drug is eliminated when a normal dose is given is Dn K which is the rate at which drug must be replaced if the peak blood level is to be maintained. Given a maintenance period t, the maintenance dose (Ds) is Dn. K.t. The total dose is therefore

$$Dt = Dn + Ds$$

$$= Dn + Dn.K.t.$$

$$= Dn (1+K.t.)$$

$$\frac{=1 + 0.693\ t}{t^{1/2.}}$$

Where K = 0.693 for 1st order kinetics; $t^{1/2}$ is the biological half life of a drug, Nelson (1957)[7] suggested a factor 'f' for calculating therapeutically effective blood levels

$$\frac{Dt = fxDn\ (1 + 0.693t)}{t^{1/2.}}$$

Even with the reduced amounts of the drug, the concentration in the blood may be higher than intended due to simultaneous release from both the immediately available and maintenance forms. Rowland and Backett criticized the approach of Nelson[7]. Speiser[9] derived a similar solution to this problem.

Mechanism Controlling Drug Availability From A Sustained Release Dosage Form:

The rate at which a drug moves from the dosage form to the depot can be prolonged in the desired manner through a control of the diffusionary process by which it is removed from the dosage form[10]. Although the precise means by which drugs are released from long acting preparations have not been clearly demonstrated, the principles on which the release is based were reported by Cooper[11] for a number of tablets. Other possible mechanisms may be involved e.g. leaching and erosion. As a tablet passes through the G.I. tract, the drug is leached out by the G.I. fluid at a rate which is independent of pH, motility and enzymes and the shell is excreted intact. In general, diffusion may be of two types:

1. Leaching Type:

Drug is partitioned with a polymeric membrane and the polymer is water-insoluble. Water solubility of the drug in the membrane constitutes the driving force of the diffusion.

2. Erosion Type:

Polymers are partially soluble in water or if one takes mixture of soluble and insoluble polymers, the membrane thus formed is partially soluble in water. Hence the membrane will be eroded at various places from which the drug will be slowly released.

Higuchi [12] reported the mechanisms of the rate of release of drugs dispersed in solid matrices. Two systems have been considered :

i. Unidirectional leaching of or extraction from a simple plain surface.

ii. Three dimensional leaching or extraction from a spherical pellet.

Bayne and place[13] studied the kinetics of osmotically controlled delivery systems after repeated dosing.

Classification Of Sustained Release Preparations:

Controlled Release preparations can generally be placed in one of the following categories[14].

A. Oral Dosage

1. Slow release dosage form

2. Delayed release preparation e.g. enteric coated products.

3. Prolonged release products.

B. Intramuscular Dosage

1. Depot Injections

2. Water immiscible injectables e.g. oily solutions of drugs.

C. Cutaneous/Subcutaneous Dosage

1. Implants e.g. contraceptive formulations

2. Transdermal preparations e.g. Nitroglycerine, estrogens etc.

D. Targeted Dosage:

1. Ocusert e.g. pilocarpine

Prolonged release drug products are often formulated to permit the establishment and maintenance of drug and/or metabolite(s) concentration at target sites for longer intervals of time than is possible with conventional ones so as to prŏvide a clinical advantage. Slow release drug products, on the other hand may be formulated to avoid the toxicity associated with a peaking effect.

Fabrication of Sustained Release Products:

Fabrication of sustained release products is possible through a number of techniques.

1. INCREASING PARTICLE SIZE OF THE DRUG IN DOSAGE FORM

To increase the particle size the surface to volume ratio is decreased as per the following equation:

$$\frac{R=(C_{1\,2/3}\pi^{1/3})\ (DC_1).\ W^{2/3}}{P^{2/3}.d.}$$

Where R= Rate of release of drug

C_1= Concentration driving the diffusion process

D= Specific constant concerned with the ability and speed with which the drug must move to be considered free of the dosage form.

π= Density of the drug pellet

W=Weight of the drug pellet

d= Distance through which drug moves from dosage form to the depot.

The surface to volume ratio can be decreased by reducing porosity, by increasing the compression force, by decreasing the adhesion and by modifying the surface of the particles etc.

Size enlargement is a method that has been used to formu-

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late sustained action sulfonamide tablets.

2. EMBEDDING THE DRUG IN A MATRIX (Skeleton):

The matrix is a uniform dispersion of a drug in a solid which is less soluble than the drug in the depot fluid. The external phase in a matrix is usually a hydrophobic material embedding the drug. Matrices are of two types:

a) Slowly eroding matrix:

In this process the active ingredients are either dissolved or suspended in a mixture of melted fats and waxes [15,16] such as bees wax, carnauba wax, hydrated fats, synthetic waxes, butyl stearate, stearic acid, castor oil etc. The melt is either dispersed by spray congealing or the solidified drug vehicle mass is milled. These granules/particles can be formulated into sustained release capsules, multilayer tablets, core coated tablets etc. The liberation of the drug is by gradual erosion.

b) Embedment in plastic matrix (Skeleton) :

The skeleton type of preparations are made by granulating active ingredients with inert plastic materials such as polymers. The liberation of the active ingredient from the dosage form is by leaching of the drug from the inert plastic skeleton or matrix [17,18].

The literature on drug release from matrix formulation is extensive. Many matrix formulation do not meet the criterion of constant availability as required for sustained release products[19].

3. BARRIER COATING :

Drug availability rate depends upon the physicochemical nature of the coating material. The barrier coating principle can be applied either to beads or granules or to the whole tablet. The release of drugs depends upon erosion or moisture permeability of the coat, which is dependent on its composition and thickness. The release mechanism is generally by dialysis as water insoluble but permeable plastics are used for coating. Only in rare cases dose release follows erosion. The development of lacquer materials of well defined permeability based on methacrylate led to suitable barrier coating dosage forms. The barrier coating principle can only be employed for water soluble drugs.

Coating of large particles, tablets and pellets is usually carried out in a rotating pan. The coating material is usually hydrophobic and applied as a solution. The pore size distribution in the coating depends, to a considerable extent, on the coat application and drying conditions for each particle in the pan. These are not uniform within the pan, nor is mixing completely random[20]. This lack of uniformity in effective coating thickness is of course one reason why its difficult to obtain precise reproducibility of release when the coated dosage unit is a single tablet. Popular sustained release products are coated pellets or granules. Here the range in effective coating thickness is used to obtain pellets or granules, whose differing rates of drug release provide the desired sustained action[21].

By varying the functional groups of acrylic resins, (Eudragit L, Eudragit Retards [22,23,24]) coatings are obtained with solubility and permeability independent of pH within the pH range of 4-8. These resins possess uniform properties over the whole pH range which is found in the G.I. tract. Thus the drug release of the active ingredients is independent of the position of the drug in the tract and is only a function of time.

Oral prolonged action formulations based on barrier coating can be prepared using one of the following methods:

– Simple film coating of the tablet

– Simple film coating of pellets or granules and filling into gelatin capsules

– Coating of the granules and compressing them to form tablets leads to fusion of film layers yielding a compact matrix which does not disintegrate.

4. REPEAT ACTION

These formulations contain two or more doses, one of which is released immediately after administration and the dose(s) released after a certain time interval or in a certain environment. This is managed by using enteric coating for the other dose. These second doses are coated by an enteric film such as cellulose acetate pthalate

The initial phase is administered around the core in the form of a sugar coat or by compression coating[25]. Once the coating has dissolved, the release of drug is similar to that of the uncoated dosage form. However, if it is displaced by a period equivalent to the transit time from the mouth to the stomach or intestine and by the time taken for the coating to dissolve.

ION EXCHANGE RESIGNS

Ion exchange resins provide a means for binding ionized drugs inside a diffusion controlling insoluble matrix [26,27]. The drug is released from these preparations according to the ionic environment which is difficult to regulate. Thus the possibility of variation in release rate is high. The utility of ion exchange resins for the formulation of sustained release products is limited. Only ionic drugs are suitable and the capacity of the resins for the drug is small.

DRUG COMPLEX FORMATION

Drugs having an amino group in the molecule like alkaloids, antihistamines and amphetamines can be complexed with tannic acid[28]. Also the preparation of methyl cellulose salts of basic amines is possible for this type of preparation.

PASSIVE-SPONGE FORMATION

The drug is dispersed in polyethelene glycol (PEG) solution shellac or polyvinyl acetate and filled into soft gelatin psules. In the interior of the capsule a sponge like skeleton formed. The active ingredient is slowly released from this croporus sponge by diffusion[29].

MISCELLANEOUS

Besides the above, other processes have been used to epare sustained release dosage forms. A hydrophilic matrix y be formed by mixing the active ingredients with non gestable hydrophilic gums and compressed into tablets. on administration hydration and gelation of the gum takes ce at the tablet-liquid interface. A viscous gel formed at the erface acts as a barrier[30]. Other methods to formulate sus-ned release products utilize the formation of polymer resin ds in which the drug is liberated in either acidic or basic vironment of the gastro-intestinal tract[31].

Presently sustained dosage forms are very widely used. A nificant rise is seen in the development of sustained action mulations for the drugs used in diseases like glaucoma, gina, diabeties, cancer, pan, cough, cold nausea, iron iciency etc[32]. Many sustained release products have been epared using different techniques and have desired rapeutics effect. The trend in research suggests that therapy l in the future be replaced by delivery systems which will cisely deliver drugs to the desired receptor site. Sustained ion forms will continue to find their place in this scheme ause its often desirable to sustain the biological effect at the eptor longer than the drug can provide.

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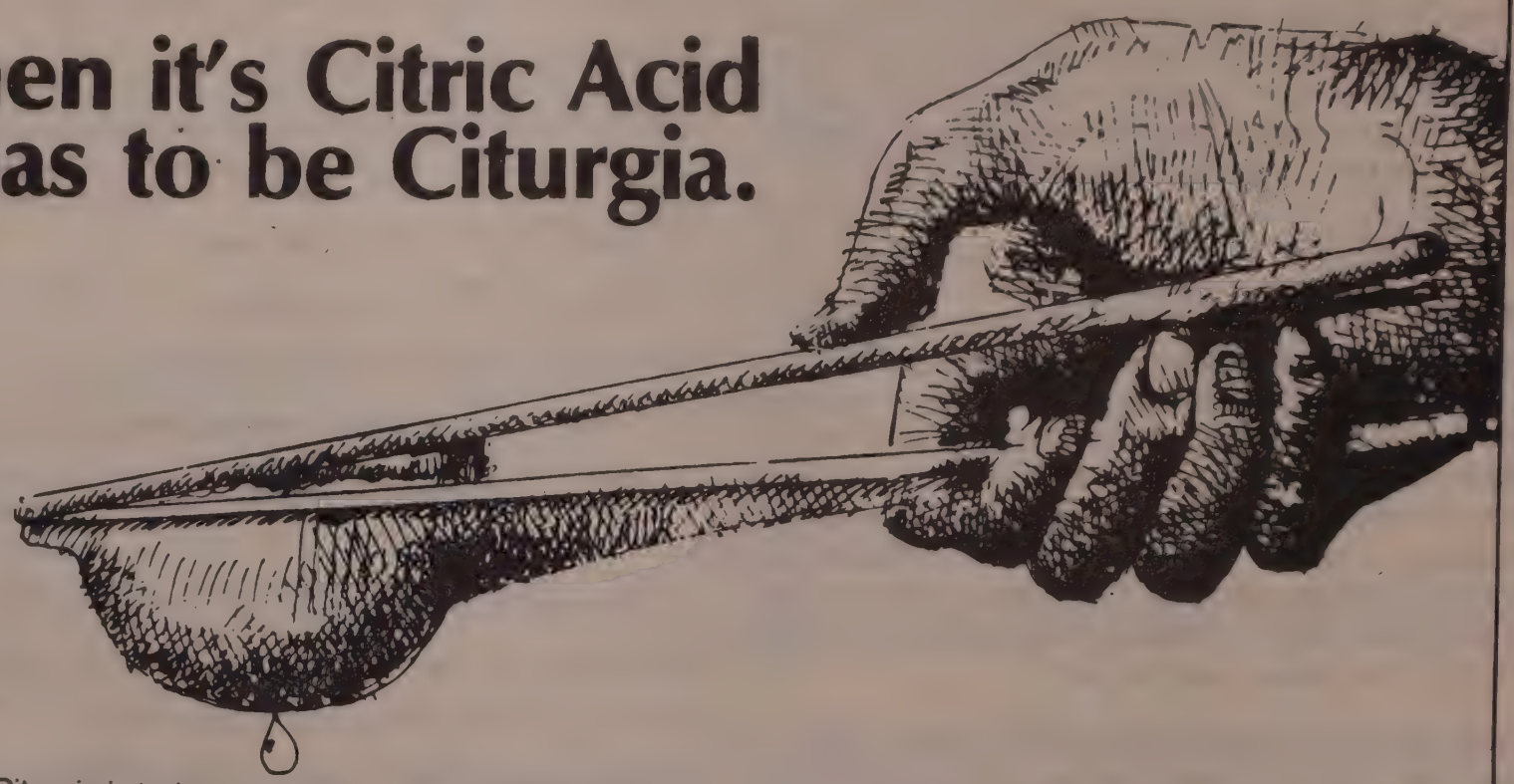

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THE Eastern PHARMACIST

25 Years Ago

August 1964

Self-Sufficiency in Drugs by 1967

MADRAS : India would be almost self-sufficient in synthetic and antibiotic drugs by 1967 after the synthetic drugs plant at Hyderabad and the antibiotics plant at Rishikesh went into production.

This was stated here by Prof. Humayun Kabir, Union Minister for Petroleum and Chemicals, in a talk with newsmen after a visit to the Surgical Instruments Factory at Nandambakkam, near here.

The Rs. 6-crore surgical factory, being established with Soviet aid, would go into full production by 1967, if not earlier, he said.

It will manufacture two-and-half million pieces of surgical instruments of 166 types every year.

Prof Kabir said that a small museum containing replicas of surgical instruments used in India at various times in the part was also proposed to be set up near the factory. Surgical instruments used in India about 2,000 years ago under the ayurvedic system would be exhibited in the museum.

Full-time Drugs Controller

CALCUTTA : The West Bengal Cabinet recently decided to place the drugs control administration in the state under a fulltime Drug Controller and to enhance penalties for offences under the Drugs and Magic remedies (Objectionable Advertisements) Act.

These are two of the four recommendations of the Drugs Inquiry Commission, which the Cabinet decided to accept and act on immediately.

The other two reommendations to be implemented immediately are reorganization of the Drug Control Laboratory and amendment of the existing Drugs Act.

In the proposed reorganization of the Drug Control Administration, in addition to the full-time Controller, Assistant Controllers and an adequate number of senior and junior Inspectors will be appointed.

On the question of amending the Drugs Act, although it is a Central Act, the State Government would write to Delhi to amend it on the lines suggested by the Commission. Besides this, there were a few other recommendations which needed to be studied and dealt with by the Centre.

ASK YOUR PHARMACIST

The medicine cabinet

"I have a bathroom cabinet full of medicines. Some old, some new. How can I tell if the medicines are still good?"

To begin with, the bathroom is just about the worst place in the home to store your medicines. Your kitchen is no better. Heat and humidity damage drugs.

All medicines deteriorate eventually, some more quickly than others. Medicines should be stored in a cool, dry place. If yours are, then you can follow these general storage guidelines:

1. Discard any liquid a month after you've opened the bottle.
2. Tablets and capsules are generally good for a year. However, coated tablets will last much longer, sometimes up to five years.
3. Ointments, creams, and gels can be kept for about six months.
4. Some special products used for acne can only be kept for 30 days. Check for an expiry date on the package.
5. Any medicine that changes color, has a moldy appearance, or develops a sediment or unusual odor should be discarded immediately.
6. Never save prescription medications for future use unless your doctor says you may.
7. Don't store medicines in the refrigerator unless your pharmacist tells you to do so.

Some medicines lose their effectiveness after a certain period; others may become harmful. Look for an expiry date on the medication. If it's passed, throw it out.

Don't throw old medicines into the garbage. You may throw away a very small amount by flushing it down the toilet, rinsing out the container, and throwing the container into the trash. If you have a larger

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amount (for example, more than 2 or 3 pills), take the medicine to your pharmacist, who will discard it for you. IT WILL NOT BE RESOLD OR USED BY ANYONE ELSE.

All medicines should be stored in a locked cabinet or box. Your bedroom is probably a good place to keep medicine if it will keep your medicines cool, dry, and out of the reach of children. No children in your home? Don't forget about visiting children and adults who act like children sometimes.

Be sure to ask your pharmacist if there are any special storing instructions for the medicines you purchase, both prescription and non-prescription. Remember not to store them in your bathroom or kitchen. Medicines can only help you if kept fresh. Store them wisely.

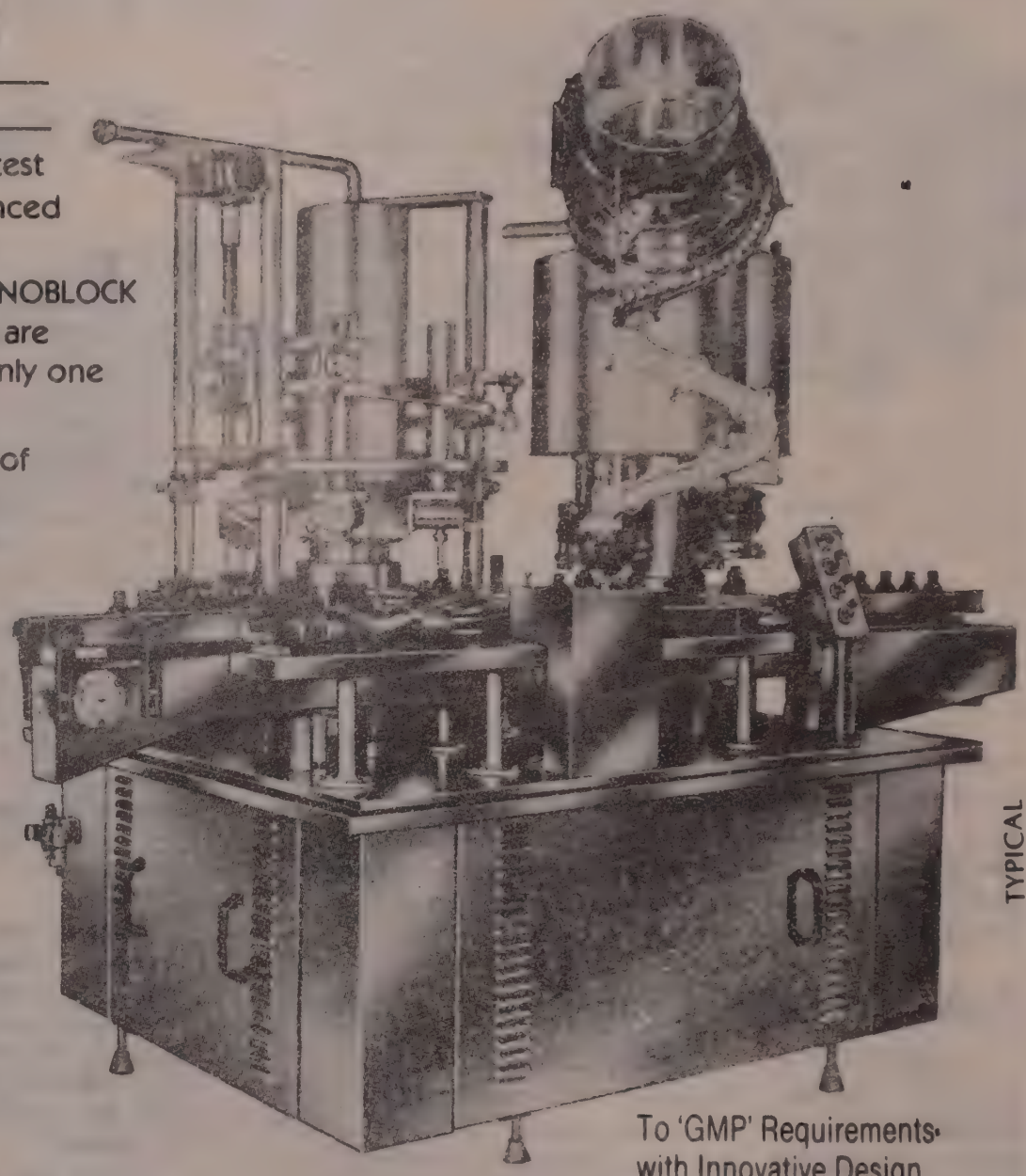
An advisory column written by The Canadian Pharmaceutical Association, Ottawa, Ontario.

TWO-IN-ONE

MONOBLOCK FILLER & SEALER

HIGHLIGHTS

1. The design of the machine is based on latest technology and is adopted in most advanced countries like U.S.A., West Germany, etc.
2. Only one operator is required to run MONOBLOCK machine as the filling and sealing sections are driven by the same motor and having only one operating panel.
3. Since the filled bottles after coming out of the Rotary Filling section are immediately sealed in the Rotary Sealer the chances of contamination are minimum.
4. There is no down time in setting the two section of monoblock machines as they are mounted on the same body
5. Requires less floor space as compared to individual machines.
6. The MONOBLOCK Filler and Sealer accommodates containers of various shapes and sizes.
7. The valves fitted to the pump assemplies are of unique and well-tried design i.e. Rotary type. No pinch cork or non-return valve is provided. No air bubbles go inside and no volume variation.
8. The machine is provided with "NO BOTTLE NO FILL" system for each individual container. Even if one container is missing, the material in the pump assembly goes back to the filler bowl, hence there will be no spillage.
9. The machine has no tubings and can be cleaned up in 30 minutes by dismentling the contact parts and assembling for product change.
10. The machine works on POSITIVE DISPLACEMENT Principle and fills accurately, with an accuracy of +0.5%.
11. The machine has centralized volume adjustment system, avoiding down-time in setting the individual pistons in the cylinders.
12. The machine has minimum number of moving parts so wear and tear is very less and is easy to maintain.
13. The MONOBLOCK FILLER is known for FAST, ACCURATE FILL WITHOUT PRODUCT SPILL.



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ATOMAT — A TOUCH OF INTERNATIONAL QUALITY

CURRENT DRUG INFORMATION

Consultant Editor: Dr Jack Thomas

Factors involved in the selection of hypnotics

By Dr Jack Thomas

In 1957, animal studies carried out with the benzodiazepine derivative, code Ro5-0690, indicated that the compound had hypnotic, sedative and anticonvulsant effects in mice and cats.

Clinical trials in humans followed, and revealed that it was clinically effective in alleviating tension and anxiety in a group of psychoneurotic patients. Following detailed clinical evaluation the drug was introduced into practice in 1960.

Ro5-0690 was the laboratory code for chlordiazepoxide, and this was the first of the benzodiazepine group of drugs.

Since 1960, thousands of benzodiazepine derivatives have been synthesised and screened pharmacologically, and about 20 or more of them have been used clinically.

In practice, although a particular benzodiazepine derivative is used preferentially for the treatment of a given condition (e.g chlordiazepoxide as an anxiolytic, diazepam as a muscle relaxant, clonazepam as an antiepileptic and temazepam and nitrazepam as hypnotics), most of the 1, 4-benzodiazepine derivatives are able to produce all of these effects, and with most of them there exists very little separation between anxiolytic and sedative properties.

Benzodiazepine receptors (1). The use of radio-labelled benzodiazepines led to the discovery of stereo-specific binding sites on nerve tissue in the mammalian central nervous system with a high affinity for benzodiazepines.

There is a good correlation between the affinity of various benzodiazepines for these binding sites and their pharmacological potencies in man and animals.

This is taken to be good evidence that they represent the pharmacological site of action of these drugs that mediate the anxiolytic, anticonvulsant, hypnotic, sedative, and muscle relaxant properties of these compounds.

Initially it was thought that there was a single homogenous class of binding sites for the benzodiazepines, but more recent evidence suggests the existence of two or more distinct neuronal binding sites.

In summary, the benzodiazepines act in the central nervous system, on the same group of binding sites, and they all possess a similar spectrum of pharmacological properties although there are variations in their potencies.

Pharmacokinetics of benzodiazepines(2). It might appear, from the above discussion, that all benzodiazepines would be of equal utility in the treatment of insomnia provided that equipotent doses were used.

However, this is not the case, and to understand why, it is necessary to consider the pharmacokinetics of this group of drugs.

For a particular benzodiazepine to exert its effects it must be present at the receptors in the central nervous system to which it binds at an appropriate concentration. There will be a gradation of the magnitude of effects as the concentration rises to, and falls from, the optimum concentration.

Following administration of a benzodiazepine either orally or parenterally, it will be absorbed into the circulation, the blood levels will rise as the drug is absorbed, and it will be carried around the body.

As approximately 20% of the cardiac output goes to the brain, and the brain is a relatively small organ, then the concentration of the drug in brain tissue will be high, since the benzodiazepines can cross the blood brain barrier readily.

When absorption is complete, the blood levels of the drug, and consequently brain levels, will fall as the drug is removed from the circulation.

That is the rate of onset of action, and the duration of hypnotic action of a benzodiazepine will be determined by its pharmacokinetic profile. The rates at which plasma levels of the various benzodiazepines in current use rise and fall following administration vary considerably.

This means that the rational selection of a benzodiazepine for use as an hypnotic should take into consideration its pharmacokinetics.

Clearance. Three independent processes can be involved in the clearance of a drug from the circulation. These are renal clearance, distribution, and metabolism.

(i) Renal clearance. As blood passes through the kidney, substances are extracted from it and voided from the body in the urine which is formed.

The mechanism of renal clearance is such that in order for a foreign molecule to be excreted into urine the substances must be water soluble. The benzodiazepines are poorly soluble in water and so they are not

excreted into urine to any great extent.

Examination of urine of a person who has taken a benzodiazepine will show that there are only traces of it present. Renal clearance does not represent a significant part of the total clearance of benzodiazepines.

(ii) *Hepatic clearance (metabolism).* If a drug cannot be cleared by the kidney because it is not sufficiently soluble in water, then the body handles the situation by converting the drug into water-soluble derivatives which can be so excreted.

Most of these metabolic reactions, although not all, occur in the liver. There are a whole range of metabolising enzymes which are capable of carrying out a variety of reactions on the foreign molecules such as: oxidation, reduction, hydrolysis, and conjugation.

Which reaction or sequence of reactions occurs to a particular drug is determined by the chemical nature of that drug. In general, it is true to say that the final compound produced is a water-soluble one which is readily excreted by the kidney, and which normally has no pharmacological action.

On the other hand, intermediate metabolites may be pharmacologically active and not be excreted by the kidney. In such a case, the duration of action of the drug is in effect a combination of the drug itself and its active metabolite.

The benzodiazepines are metabolised extensively, particularly by several different enzymes systems in the liver.

Since active metabolites are generated that are metabolised more slowly than the parent compound, the duration of action of many benzodiazepines bears little relation to the elimination rate of the drug administered.

For example, the half-life of flurazepam in plasma is two to three hours, but that of N-desalkylflurazepam, a major active metabolite, is 50 hours or more. On the other hand, the rate of metabolism of those benzodiazepines which are inactivated by the initial reaction is an important determinant of their duration of action.

An example of such a drug is temazepam. Temazepam contains an hydroxyl group which allows it to be metabolised directly to a glucuronide conjugate which is inactive and water-soluble.

Compounds such as diazepam, clorazepate, chlordiazepoxide, and flurazepam are initially metabolised to long half-life active metabolities, while triazolam and alprazolam are metabolised to short half-life intermediates.

(iii) *Distribution.* Following absorption of a benzodiazepine there is a rapid diffusion of it into the central nervous system as described above.

This initial distribution phase is followed by a phase of redistribution into tissues which are less well perfused. Muscle and fat are two such tissues.

In such a circumstance, the plasma levels of the drug fall, not because the drug has been excreted, but because it has been re-distributed.

In the regimens used for sedation at night the rate of re-distribution can sometimes have a greater influence on the duration of the hypnotic actions than the rate of metabolism.

Once a drug has been sequestered into muscle and fat, it then slowly diffuses out of these tissues, thus providing a reservoir which maintains plasma levels of it for a prolonged period. This can be associated with prolonged drowsiness on the following day.

A further complication of re-distribution is that with regular use the total amount of the drug in the body gradually rises, and the clearance of this may take a considerable period of time following withdrawal of the drug.

Drugs which are likely to be re-distributed are fat soluble ones which are metabolised relatively slowly. If the plasma levels of drugs are plotted against time following the peak level, the curve obtained indicates whether a drug is re-distributed or not.

If the slope of the curve falls rapidly immediately after the peak level has been attained, and then after a period of time falls much slower, this is taken to indicate that the drug has been re-distributed.

The initial rapid fall represents the re-distribution phase and the slower second fall represents the rate at which the drug is metabolised.

If, on the other hand, the rate of fall of plasma levels of the drug is constant with time, then this is taken to indicate that the drug is being cleared essentially by either renal clearance or hepatic clearance, and not being significantly re-distributed.

In practice the logarithm of plasma concentration is plotted against time in such studies, and the terms monoexponential decay and biexponential decay are used to describe the two types of clearance from plasma.

In summary, a rapid fall in plasma levels can result from either clearance or re-distribution. If the cause is re-distribution, the drug is still in the body for long periods, and can be expected to cause residual effects.

Absorption. The rate of absorption of drugs given orally can be influenced by a number of factors.

These include: the physicochemical properties of the drug (in particular water solubility), the pharmaceutical formulation, the presence of food in the stomach, how the drug is taken, and the position of the person.

Many studies on the rate of absorption of drugs are carried out on subjects who have fasted prior to the administration of the drug, and so give a measure of the intrinsic ability of the drug to be absorbed.

In general, the benzodiazepines are adequately absorbed and so are useful for difficulties associated with the onset of sleep. However, some are only slowly absorbed, e.g. oxazepam and loprazolam.

As a general rule oral absorption of drugs is most rapid from aqueous solutions, followed by soft capsules in which the drug is in solution in a solvent within the capsule, hard gelatine capsules, and finally from tablets.

Temazepam is a drug which illustrates the effect of formulation on the rate of absorption.

It is absorbed from soft gelatine capsules with a mean delay to peak plasma level of less than an hour. However, from hard gelatine capsules the rate of absorption is slower, with a mean delay to peak plasma levels of around two hours(5).

Capsules, both hard and soft, have a greater tendency to adhere to the oesophagus than do tablets, although tablets may also be held up in the oesophagus.

If this occurs, then the absorption of the drug will be retarded, and if the drug happens to be ulcerogenic (e.g. potassium chloride) an ulcer may be formed in the oesophagus.

Patients should always be recommended to take solid dose forms, and particularly capsules, with a half a glass or so of fluid, except in those cases were there is a special reason why this should not be done, e.g. sublingual tablets.

The probability of a solid dose form being held up in the oesphagus is increased if the patient is lying down when the medication is taken, and so patients should be advised to take hypnotics before going to bed.

In general, food in the stomach delays the transit of drugs to the small intestine where absorption takes place, and so taking medication on an empty stomach will provide conditions for the most rapid attainment of peak plasma levels of the drug.

Benzodiazepines as hypnotics. In a recent review of hypnotics, Nicholson(3) concludes that: "It is now appreciated that the most appropriate use of hypnotics is in the indivudal with insomnia of recent origin.

"Low doses of the hypnotic with the most appropriate pharmacokinetic profile should be used for the shortest time, and then only as required.

"Indeed, it would appear that hypnotics tend to be used mainly for only 1 or 2 days, or for less than 2 weeks when needed more regularly. The place of hynotics in chronic insomnia is less certain.

"Their careful use may be of benefit, though it must be part of a well defined

clinical strategy, and assessment of the patient is essential to indentify any specific conditions which would impair sleep.''

In this review the author classifies benzodiazepines into six groups according to their pharmacokinetic profiles as related to their use as hypnotics.

These are: slow absorption (oxazepam); slow elimination of parent compound or metabolite A (flurazepam); relatively slow elimination, but marked distribution may lead to a short duration of action B (diazepam, flunitrazepam, nitrazepam); relatively rapid elimination and marked distribution phase in appropriate formulations C (temazepam); rapid elimination; ultrarapid elimination (midazolam) (4).

A. Residual effects likely and accumulative on continued nightly ingestion inevitable.
B. Residual effects and accumulative on daily ingestion.
C. Free of residual effects and of significant accumulation on daily ingestion.

Daytime effects of hypnotics. If the condition being treated is simple insomnia of short duration, then it is undesirable to have hangover effects the following morning.

Apart from being unpleasant, they can also be dangerous with people driving to work and even using equipment around the home. If, on the other hand, the patient is being treated for anxiety states, then residual anxiolytic effects the following morning are acceptable.

Nicholson in his review(3) gives a ''simplified guide to the use of hypnotics'' in which he classifies them into three groups.

Group 1 are described as being ''long-acting hypnotics with activity persisting into the next day because of residual effect of accumulation on daily ingestion''. Drugs available in Australia included in this class are: flurazepam, diazepam, nitrazepam, and flunitrazepam.

Group 2 are described as ''short-acting hypnotics which are free of residual effects the next day and of accumulation on daily ingestion'', and this group includes temazepam, and midazolam.

There are no examples of drugs listed by Nicholson in Group 3 available in Australia.

Other studies which have been reported recently on the residual effects of hypnotics have shown that the elimination half-life is important in influencing the incidence and magnitude of such effects.

It is stated by Hindmarch(6) that ''residual effects are dose related and more likely if the elimination half-life is greater than 12 hours.''

He compared the residual effects of temazepam (20mg), triazolam (0.25mg), nitrazepam (5mg), flurazepam (15mg), or placebo, and reported that ''neither study showed a residual activity that was likely to impair performance following temazepam (20mg), indicating the usefulness of this drug in the management of idiopathic insomina and sleep difficulties introduced by changes in scheduling of sleep, i.e. intercontinental travel or shift work.''

In another study(7), the effects of triazolam (0.5mg) and temazepam (30mg), on immediate and delayed recall in normal and insomniac subjects were investigated.

It was found that ''in the tests of delayed recall, triazolam caused a consistent anterograde amnestic effect. No significant impairment of delayed recall was observed in the temazepam study.''

It is thought that anterograde amnesia is a dose-related effect of benzodiazepines, and that compounds with a high affinity for benzodiazepine receptors, i.e. those with a low recommended dosage regimen, cause this type of amnesia more often than lower affinity compounds.

Jet lag and hypnotics. Hindmarch(6) concluded from his studies that temazepam could be used for the management of jet lag. This has since been studied in depth(8).

The study was double-blind placebo-controlled and assessed the next morning effects of a bedtime dose of temazepam (20mg) in 14 male athletes.

The study was aimed at determining a satisfactory agent to give to international athletes who have to travel great distances to athletic meets and then perform soon after arriving, when jet lag and loss of sleep can be a problem.

It was stated that temazepam (20mg) ''is best administered at bedtime if the event is scheduled for the next afternoon; for morning events we recommend the lower dosage of 10mg temazepam'', and ''in connection with westward or eastward air travels, the athletes showed prompt adjustment of their day–night biorhythms without hangover.''

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(2) The pharmacokinetics of benzodiazepines are described in: S.C. Harvey, *The Pharmacological Basis of Therapeutics,* 7th Edition. Eds. A.G. Gilman, L.S. Goodman, T.W. Rall, and F. Murad. MacMillan, New York, 1985, pp 347 – 349.

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(4) Only benzodiazepines available in Australia have been listed. The list given in the original article contains more examples of benzodiazepines.

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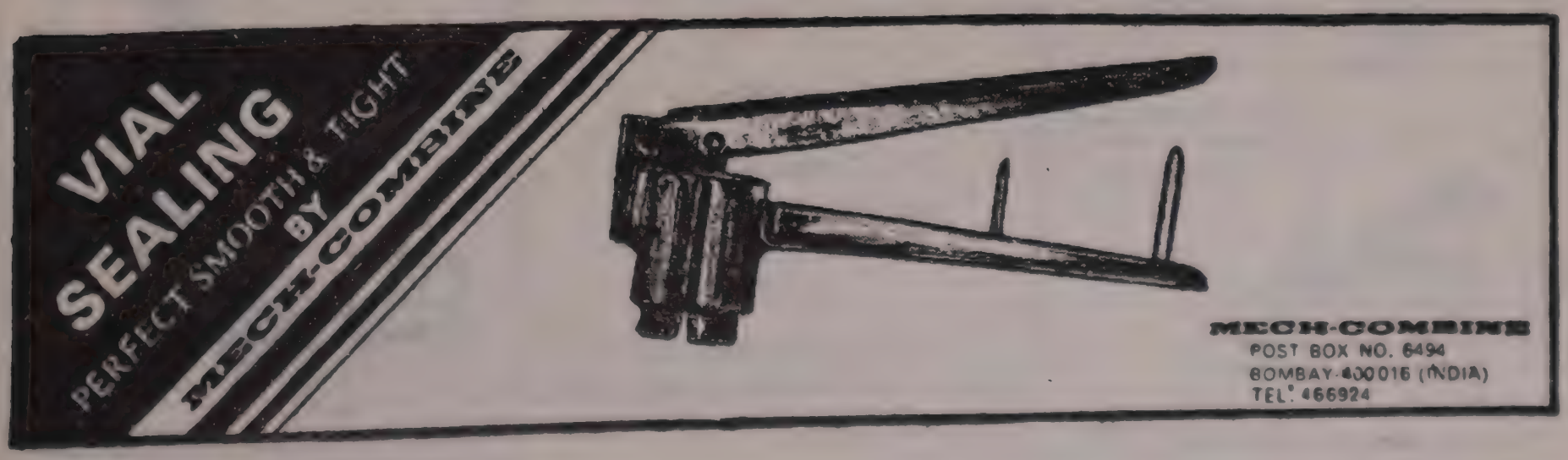

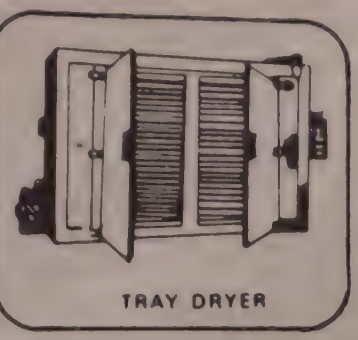

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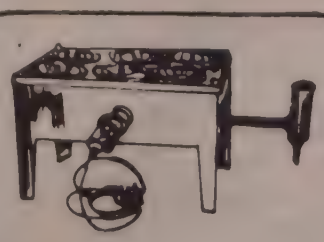

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LABEL GUMMING MACHINE

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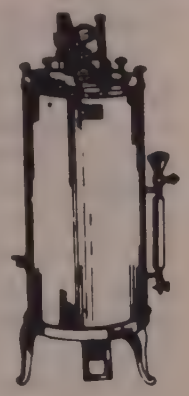

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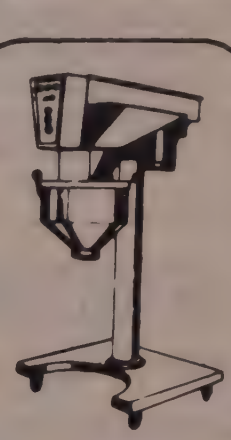

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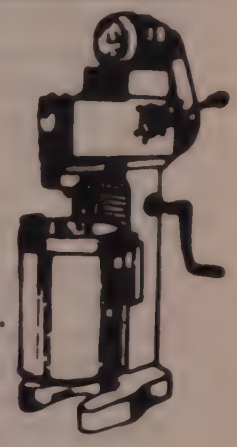

PLANETORY MIXER

P. P. CAP SEALING MACHINE (PADDLE TYPE)

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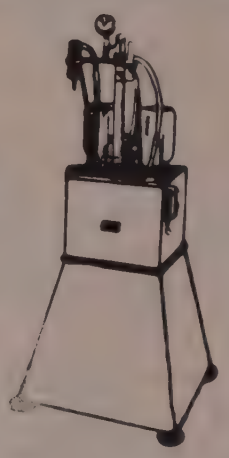
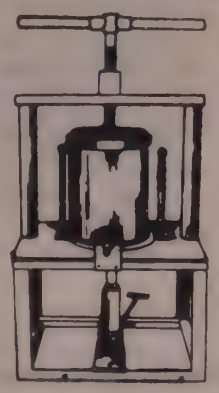


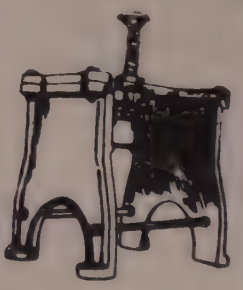
BOTTLE FILLING MACHINE

MEMBRANE FILTER HOLDER WITH PRESSURE TANK

STRIP PACKAGING MACHINE (SEMI AUTOMATIC)



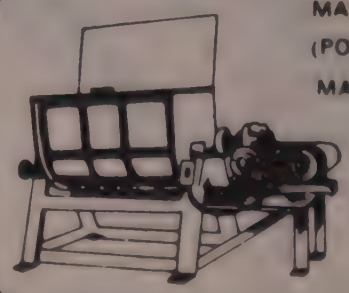
TINCTURE PRESS



BIOCHEMIC TABLET MAKING MACHINE

TABLET HARDNESS TESTER

SPARKLER TYPE FILTERATION UNIT



MASS MIXER (POWDER MIXING MACHINE)

Guide to international travel immunisation

Symbols

- ○ **Vaccination certificate for travellers coming from infected areas.**
- ♦ **Vaccinations that are essential for entry into the country concerned or Australia, where a certificate is required.**
- ● **Vaccination recommended for protection against disease.**

The table provides guidelines for immunisation which presently can be considered sensible.

It should be noted that conditions in many countries are continually changing and up-to-the-minute information can be obtained by enquiry to the Commonwealth Department of Community Services and Health in each state capital city.

Table I

GUIDELINES FOR IMMUNISATION

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Afghanistan		●			●	●	●	●	●	○
Andorra							●	●	●	
Antigua		●					●	●		○
Albania	○						●	●	●	○
Algeria		●			●	●	●	●	●	○
Angola	●	●		●	●	●	●	●	●	● ♦
Argentina		●			●		●	●	●	
Austria							●	●	●	
Azores							●	●	●	○
Bahamas		●					●	●	●	○
Bahrain	●	●				●	●	●	●	○
Bangladesh	●	●	●		●	●	●	●	●	○
Barbados		●					●	●	●	○
Belize		●			●	●	●	●	●	○
Benin	●	●		●	●	●	●	●	●	♦

• continued overleaf

Cholera

Cholera is a bacterial infection that causes watery diarrhoea, which can lead to dehydration and, in some cases, death.

Although cholera was once confined largely to Asia, it is now found in Africa, the Middle East. Eastern Europe and the South Pacific. Cholera, like typhoid, is transmitted by contaminated food or water.

At present cholera vaccine is thought to provide 50–70% protection for between three and six months. Travellers should be advised to carefully select food and drinks even after immunisation.

Travellers visiting an area after a recent outbreak of cholera may be required to either demonstrate proof of immunisation or undergo compulsory immunisation by the public health authorities.

Hepatitis A

The risk of hepatitis A for Australians travelling abroad will depend on living conditions, the incidence and prevalence of the disease in areas visited and the length of the visit.

Normal Immunoglobulin (Human) may not always prevent infection but it can be expected to modify the resulting disease so that it is mild, or undetectable clinically. Vaccines to confer active immunity are under development, but none has been approved for use at the present time.

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Japanese Encephalitis

Japanese encephalitis is a serious mosquito borne viral disease which is prevalent in many Asian countries. The risk to short-term travellers and those who are not leaving urban areas is very low. Long-term visitors (i.e. more than 12 months) to "risk" areas should explore the possibility of immunisation with their doctor. A vaccine is available, but only on individual patient usage approval from the Department of Community Services and Health in Canberra.

Malaria

The risk of contracting malaria occurs in tropical and sub-tropical areas. Adequate precautions should be taken against mosquito bites, e.g. the use of insect repellants and covering body and limbs with clothing, particularly at dusk. Travellers to malarial areas should seek advice from the Department of Community Services and Health in their state capital city on the need for anti-malaria treatment.

Meningococcal Meningitis

Meningitis may be caused by a number of bacteria or viruses. Meningococcal meningitis is one of the most serious bacterial diseases and can be fatal. Meningococcal disease is transmitted from person to person by respiratory droplets (coughing and sneezing).

A single dose of meningococcal vaccine is recommended for travellers visiting areas where meningococcal disease types A and C are present in epidemic proportions.

Poliomyelitis

Travellers who intend visiting countries where there may be a risk of contracting polio should have a booster dose of oral polio vaccine every 10 years. For travellers who have previously only had a partial course of vaccine, the primary series should be completed.

Rabies

Rabies is a fatal viral disease resulting from the bite of an infected animal. Rabies infected animals are found in most countries.

The following countries are reported as rabies-free: Australia, Bermuda, some of the Caribbean islands, Finland, Gibralta, Iceland, Ireland, Japan, Malta, New Zealand, Norway (except Svalbard), the Pacific Islands, Papua New Guinea, Portugal, Spain. Sweden and the United Kingdom.

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Bhutan	●	●			●	●	●	●	●	○
Bolivia		●			●	●	●	●	●	● ♦
Botswana					●			●	●	
Brazil				●	●	●	●	●	●	● ♦
Brunei	●	●	●				●	●	●	○
Bulgaria							●	●	●	
Burkina Faso	●	●		●	●	●	●	●	●	● ♦
Burma	●	●	●	●	●	●	●	●	●	○
Burundi	●	●		●	●	●	●	●	●	○
Cameroon	●	●		●	●	●	●	●	●	♦
Canada								●		
Canal Zone, Panama		●			●		●	●	●	♦
Cape Verdi Islands	●	●		●	●	●	●	●	●	○
Cayman Islands		●					●	●	●	
Cent. African Rep.	●	●		●	●	●	●	●	●	♦
Chad	●	●		●	●	●	●	●	●	♦
Chile		●						●	●	
China		●	●		●	●		●	●	○
Columbia		●			●	●	●	●	●	● ♦
Comoros	●	●		●	●	●	●	●	●	●
Congo	●	●		●	●	●	●	●	●	♦
Cook Islands								●	●	
Costa Rica		●			●		●	●	●	
Cuba		●					●	●	●	
Cyprus	●	●					●	●	●	
Czechoslovakia								●		
Denmark								●		
Djibouti	●	●		●	●	●	●	●	●	● ○
Dominica		●			●		●	●	●	○
Dominican Republic		●			●	●	●	●	●	
Ecuador		●			●	●	●	●	●	♦
Egypt		●		●	●	●	●	●	●	○
El Salvador		●			●	●	●	●	●	○
Equatorial Guinea	●	●		●	●	●	●	●	●	● ♂
Ethiopia	●	●		●	●	●	●	●	●	● ○

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Fiji								●	●	○
Finland								●		
France								●		
Gabon	●	●		●	●	●	●	●	●	● ♦
Gambia	●	●		●	●	●	●	●	●	● ♦
German Dem. Rep.							●	●		
Germany (West)								●		
Ghana	●	●		●	●	●	●	●	●	● ♦
Greece							●	●	●	○
Grenada		●						●	●	○
Guam			●					●	●	
Guatemala		●			●	●	●	●	●	○
Guiana (French)		●			●	●	●	●	●	♦
Guinea	●	●		●	●	●	●	●	●	● ♦
Guinea Bissau	●	●		●	●	●	●	●	●	●○
Guyana		●			●	●	●	●	●	●○
Haiti		●			●	●	●	●	●	○
Honduras		●			●	●	●	●	●	○
Hong Kong		●	●			●	●	●	●	
Hungary							●	●	●	
India	● ♦	●	●	●	●	●	●	●	●	○
Indonesia	●	●	●		●	●	●	●	●	○
Iran	●	●			●	●	●	●	●	○
Iraq	●	●			●	●	●	●	●	○
Ireland								●		
Israel	●	●				●	●	●	●	
Italy							●	●	●	
Ivory Coast	●	●		●	●	●	●	●	●	● ♦
Jamaica		●					●	●	●	○
Japan			●					●		
Jordan	●	●				●	●	●	●	
Kampuchea	●	●	●		●	●		●	●	
Kenya	●○	●		●	●	●	●	●	●	●○

Unless the traveller is known to be particularly at occupational or similar risk immunisation is not recommended. However, travellers should be counselled about the risks of handling animals in rabies-infected areas, and advised that animal bites, especially if unprovoked, should not be ingored. Following a thorough local cleansing of the wound, expert medical opinion should be sought without delay.

The National Health & Medical Research Council guidelines provided in "Immunisation Procedures" should be consulted for details of pre- and post-exposure prophylaxis.

Tetanus

Tetanus occurs worldwide and remains an important cause of death in many countries in Asia, Africa and South America.

Tetanus is caused by bacteria which can grow well in even the smallest skin wounds. Severe painful muscle spasms occur after an incubation period of 7–10 days and death can occur from respiratory failure. Wounds which favour the growth of tetanus include compound fractures, penetrating wounds, wounds containing foreign bodies — especially wood spinters — wounds complicated by some types of infections and those where there has been extensive damage such as cuts and burns. However, tetanus may occur in the absence of an obvious tetanus-prone wound.

Tetanus immunisation is normally part of routine childhood immunisation in Australia. Although immunity to the complete immunisation course is long lasting, it is sensible for travellers to maintain immunity with booster doses of tetanus vaccine, or if diphtheria boosting is also required, with combined diphtheria–tetanus vaccine, every 10 years.

Typhoid

Typhoid is an infection caused by bacteria of the Salmonella group. It occurs worldwide but is more common in developing countries than in Europe, North America, Australia and New Zealand. Typhoid is transmitted by contaminated food, water or ice. Shellfish taken from sewage contaminated beds, raw fruits, vegetables, milk and milk products contaminated by the hands of carriers cause significant problems in some parts of the world. Flies can also infect foods.

Although immunisation is not a legal requirement for entry into any country, protection against this disease is a sensible precaution and can be obtained by immuni-

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Fiji								●	●	○
Finland								●		
France								●		
Gabon	●	●		●	●	●	●	●	●	● ♦
Gambia	●	●		●	●	●	●	●	●	● ♦
German Dem. Rep.							●	●		
Germany (West)								●		
Ghana	●	●		●	●	●	●	●	●	● ♦
Greece							●	●	●	○
Grenada		●						●	●	○
Guam			●					●	●	
Guatemala		●			●	●	●	●	●	○
Guiana (French)		●			●	●	●	●	●	♦
Guinea	●	●		●	●	●	●	●	●	● ♦
Guinea Bissau	●	●		●	●	●	●	●	●	●○
Guyana		●			●	●	●	●	●	●○
Haiti		●			●	●	●	●	●	○
Honduras		●			●	●	●	●	●	○
Hong Kong		●	●			●	●	●	●	
Hungary							●	●	●	
India	● ♦	●	●	●	●	●	●	●	●	○
Indonesia	●	●	●		●	●	●	●	●	○
Iran	●	●			●	●	●	●	●	○
Iraq	●	●			●	●	●	●	●	○
Ireland								●		
Israel	●	●				●	●	●	●	
Italy							●	●	●	
Ivory Coast	●	●		●	●	●	●	●	●	● ♦
Jamaica		●					●	●	●	○
Japan			●					●		
Jordan	●	●				●	●	●	●	
Kampuchea	●	●	●		●	●		●	●	
Kenya	●○	●		●	●	●	●	●	●	●○

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• from previous page

sation with either convenient oral capsules or the traditional injectable vaccine.

The course of three capsules should be completed about 10 days prior to possible exposure to typhoid. If the traveller is also taking anti-malaria tablets, the course of oral vaccine should be completed one week before starting anti-malarial treatment. The oral vaccine will give protection for approximately one year. Two doses of injectable vaccine, about four weeks apart, will give immunity for three years.

Travellers immunised previously with the traditional injectable vaccine can boost their immunity with either a full course of capsules or a single injection.

Yellow Fever

Yellow fever is an acute disease caused by a virus which is transmitted by mosquito bites. It usually causes fever, vomiting and jaundice. It can cause liver and kidney damage and may be fatal.

Yellow fever is found in some parts of Central South America and Africa. Some countries still require a certificate of immunisation from travellers who are either entering the country or who have recently visited a country where yellow fever is endemic. Travellers to these areas should seek advice from the Commonwealth Department of Community Services and Health in their state capital city on the need for immunisation.

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Kiribati								●	●	○
Korea (North)		●	●			●		●	●	
Korea (South)		●	●			●		●	●	
Kuwait	●	●				●	●	●	●	
Laos (Lao)	●	●	●		●	●	●	●	●	○
Lebanon	●	●				●	●	●	●	○
Lesotho	○♦	●			●			●	●	○
Liberia	●	●		●	●	●	●	●	●	♦
Libya		●			●	●	●	●	●	○
Luxemburg							●	●		
Macao		●	●					●	●	
Madagascar	●○	●		●	●	●	●	●	●	●○
Madeira		●					●	●	●	○
Malawi	●	●		●	●	●	●	●	●	○
Malaysia	●	●	●		●			●	●	○
Maldives	●	●	●			●	●	●	●	○
Mali	♦	●		●	●	●	●	●	●	♦
Malta	○							●	●	○
Mauritania	●	●		●	●	●	●	●	●	♦
Mauritius	●	●		●	●		●	●	●	●♦
Mexico		●			●	●	●	●	●	○
Monaco								●	●	
Mongolia		●	●	●			●	●	●	
Monserrat		●					●	●	●	○
Morocco		●			●	●	●	●	●	
Mozambique	●	●		●	●	●	●	●	●	○
Namibia		●			●	●		●	●	○
Nauru		●						●	●	○
Nepal	●	●	●	●	●	●	●	●	●	○
Netherlands							●	●		
New Caledonia	○	●						●	●	○
New Zealand								●		
Nicaragua		●			●	●	●	●	●	○
Niger	●	●		●	●	●	●	●	●	♦
Nigeria	●	●		●	●	●	●	●	●	♦

• continued

References

(1) *Vaccination Certificate Requirements and Health Advice for International Travel.* (Situation as at Jan 1, 1988) World Health Organisation, Geneva.

(2) *Immunisation Procedures.* National Health and Medical Research Council.

(3) *Health Information for International Travel.* Commonwealth Department of Health.

(4) *Communicable Diseases Intelligence Bulletin* No 88/5, 14 March 1988.

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Niue								●	●	○
Norway								●		
Oman	●	●			●	●	●	●	●	○
Pakistan	●○	●	●		●	●	●	●	●	○
Panama		●			●		●	●	●	●
Papua New Guinea		●			●	●		●	●	○
Paraguay		●			●	●	●	●	●	○
Peru		●			●	●	●	●	●	●♦
Philippines		●	●		●	●	●	●	●	○
Pitcairn Island	○							●	●	○
Poland							●	●		
Polynesia (French)								●	●	○
Portugal		●					●	●	●	○
Puerto Rico		●						●	●	
Qatar	●	●				●	●	●	●	○
Reunion Islands	●	●		●	●		●	●	●	○
Romania								●	●	
Rwanda	●	●		●	●	●	●	●	●	♦
St Helena								●	●	
St Lucia		●					●	●	●	○
St Vincent/Grenadines		●					●	●	●	○
Samoa								●		○
Sao Tome/Principe	●	●		●	●	●	●	●	●	♦
Saudi Arabia	●	●		●♦	●	●	●	●	●	○
Senegal	●	●		●	●	●	●	●	●	♦
Seychelles	●	●		●	●		●	●	●	●
Sierra Leone	●	●		●	●	●	●	●	●	●♦
Singapore	●						●	●	●	○
Soloman Islands					●			●	●	○
Somalia	●○	●		●	●	●	●	●	●	●○
South Africa		●			●			●	●	○
Spain		●						●	●	
Sri Lanka	●	●	●		●	●	●	●	●	○

• continued

Lack of compliance to drug therapy related to surgical procedures

About one quarter of patients undergoing operations are taking drugs concurrently (1). Periods of fasting perioperatively tend to make normal drug taking difficult to maintain, and there have been reports that compliance on the day prior and following elective surgery is poor. A study has been carried out in the UK to assess whether patients fasting before and after their operation received their prescribed drugs (2).

All drugs prescribed and administered to patients admitted consecutively to two general surgical wards over a three-month period were recorded, without the junior medical staff or nursing staff being aware that the study was being carried out. A total of 170 patients were studied. "The operations performed mainly comprised operations for varicose veins, herniorrhaphies, and abdominal procedures; cardiac, neurosurgical, and orthopaedic operations were not included."

A total of 1746 doses were involved during the day of the operation and the day following.

It was found that "256 (15%) were not administered. All prescriptions of analgesics and premedicants were given; when these were excluded the proportion of prescriptions that were not given rose to 29%. The prescriptions omitted included 38 out of 95 for drugs for cardiovascular disease, 34 out of 103 for drugs for respiratory diseases, and 10 out of 61 for drugs for endocrine disorders."

The authors state that "if the practice of withholding drugs from patients having operations is widespread it may introduce variability in response during the perioperative period."

1. D.J.R. Duthie, J.N. Montgomery, A.A. Spence, and W.S Nimmo. Concurrent drug therapy in patients undergoing surgery. *Anaesthesia*, 1987, **42**, 305–311.

2. R. Wyld, and W.S. Nimmo. Do patients fasting before and after operation receive their prescribed drug treatment? *British Medical Journal*, 1988, **296**, 744.

NEWS NOTE

Possible complications associated with use of activated charcoal

Activated charcoal is often recommended as part of the treatment of poisoning by drug overdose. A case has recently been reported in which the use of it was associated with what is described as a "costly and avoidable complication".

The patient was a 32-year-old man who was admitted two hours after a serious suicide attempt by self poisoning with amitriptyline (85 25mg tablets) and chlorpromazine (50 50mg tablets). "After intubation he received gastric lavage followed by activated charcoal (50g). Over the next 36 hours he was given 300g of activated charcoal." He recovered and was transferred to a psychiatric unit. For the following 10 days he was mobile and maintained a good fluid intake. He was treated with danthron for constipation without effect. This was followed by more vigorous treatment with enemas, suppositories, and an attempted manual evacuation, all without effect. By the 12th day he was treated in a surgical unit for an anal stretch and manual evacuation of under general anaesthesia.

It was found that the impacted mass consisted mainly of charcoal "resembling a barbecue briquette".

It was concluded that "the combination of the anticholinergic action of both drugs taken in overdose together with ¾lb of high residue charcoal led to this result".

The authors state that "it is important to be aware of this complication — and furthermore, the early and vigorous treatment of constipation may help prevent surgical intervention".

1. I.M. Anderson, and C. Ware. Syrup of ipecacuanha, *British Medical Journal*, 1987, **294**, 578.

Amitriptyline HCL — *Endep* (Alphapharm), *Amitrip* (CP Protea), *Tryptanol* (Frosst), *Saroten* (Nicholas Kiwi), *Laroxyl* (Roche).

Chlorpromazine HCL — *Protran* (CP Protea), *Largactil* (M & B)

Charcoal Activated — *Karbons Tablets* (Eagle), *Charcocaps* (Key).

FEATURE

• from previous page

	Cholera	Hepatitis A	Japanese Encephalitis	Meningococcal Meningitis	Malaria	Polio-myelitis	Rabies	Tetanus	Typhoid	Yellow Fever
Sudan	●○	●		●	●	●	●	●	●	◆
Surinam		●			●	●	●	●	●	●○
Swaziland					●			●	●	○
Sweden								●		
Switzerland								●		
Syria	●	●			●	●	●	●	●	○
Taiwan		●	●				●	●	●	
Tanzania	●◆	●		●	●	●	●	●	●	●○
Thailand	●	●	●		●	●	●	●	●	○
Togo	●	●		●	●	●	●	●	●	◆
Trinidad/Tobago		●					●	●	●	●◆
Tunisia		●			●	●	●	●	●	○
Turkey	●	●			●	●	●	●	●	
Tuvalu		●						●	●	○
Uganda	●	●		●	●	●	●	●	●	●
United Arab Emirates	●	●			●	●	●	●	●	○
United Kingdom								●		
USA								●		
USSR			●		●		●	●	●	
Uruguay	●	●					●	●	●	
Vanuatu		●			●			●	●	
Venezuela		●			●	●	●	●	●	◆
Vietnam	●	●	●	●	●	●	●	●	●	○
Virgin Islands		●					●	●	●	
Yemen Arab Rep	◆	●			●	●	●	●	●	○
Yemen Dem Rep	◆	●			●	●	●	●	●	○
Yugoslavia		●					●	●	●	
Zaire	●	●		●	●	●	●	●	●	◆
Zambia	●	●		●	●	●	●	●	●	●○
Zimbabwe	●	●		●	●	●	●	●	●	●○

Antipyrine and Oestrogens

Conjugated oestrogen had no significant effect on antipyrine volume of distribution, elimination half-life, or clearance.

Conjugated oestrogens are widely recommended for postmenopausal women to control the vasomotor symptoms of menopause and for the prevention of oestrogen-deficiency-induced osteoporosis. It has been reported that a number of drugs which are cleared by oxidative metabolism interact with oestrogens, and this has led to an investigation of the effects of conjugated oestrogen intake on the kinetics of antipyrine(1). Antipyrine disposition is commonly used as an index of drug oxidising capacity.

Twenty-two healthy women were used in the trial. Eleven of them had been taking conjugated oestrogen preparations for at least three months, and the other eleven had not taken any such preparation. The two groups were matched as closely as possible for smoking patterns, age and body weight. Antipyrine was given (1 to 1.2 g IV) over a period of five minutes and venous blood samples collected serially for up to 24 hours. The samples were analysed for antipyrine.

Pharmacokinetic analysis of the data obtained showed that there was no difference between the oestrogen treated group and controls with regard to antipyrine volume of distribution, elimination half-life, or clearance.

The clearance of diazepam (2), prednisolone (3), and butaperazine (4) are impaired by concomitant administration of conjugated oestrogens but the clearance of alprazolam (2) is not affected.

It was concluded that "thus there is no straightforward means of predicting whether and to what extent clearance of a specific oxidatively metabolized drug may be altered by coadministered oestrogen-containing medication."

1. J.M. Scavone, D.J. Greenblatt, and G.T. Blyden. Antipyrine pharmacokinetics in women receiving conjugated estrogens. *Journal of Clinical Pharmacology*, 1988, **28**, 463 – 466.

2. A. Locniskar, D.J. Greenblatt, J.M. Scavone, and R.I. Shader. Effect of conjugated estrogens or tricyclic antidepressants on the kinetics of diazepam, alprazolam and lorazepam. *Clinical Pharmacology and Therapeutics*, 1986, **39**, 208.

3. L.E. Gustavson, U.F. Legler, and L.Z. Benet, Impairment of prednisolone disposition in women taking oral contraceptives or conjugated estrogens. *Journal of Clinical Endocrinology and Metabolism*, 1986, **62**, 234 – 237.

4. M.K. El-Yousef. Effects of conjugated estrogens on plasma butaperazine levels. *Psychopharmacology* (Berlin), 1974, **39**, 234 – 237.

Oestrogen preparations available:

Estigyn (Duncan Flockhart), *Honvan* (Bristol), *Oestradiol Implants Organon* (Organon), *Ogen* (Abbott), *Ovestin* (Organon), *Premarin Tablets* (Ayerst), *Primogyn C* (Schering P/L), *Primogyn Depot* (Schering P/L), *Progynova* (Schering P/L).

Alprazolam — *Xanax* (Upjohn).

Diazepam — *Antenex* (Alphapharm), *Diazemuls* (Pharmacia), *Ducene* (Sauter), *Pro-Pam Tablets* (CP Protea), *Valium* (Roche).

Prednisolone — *Adnisolone Tablets* (Nelson), *Delta-Cortef Tablets* (Upjohn), *Deltasolone* (Rorer), *Panafcortelone* (CP Protea), *Solone Tablets* (Fawns & McAllan).

Prednisolone Acetate — *Scherisolon* (Schering P/L).

Prednisolone Stearoyogoycolate — *Sintisone Tablets* (Sigma).

Table 2

NORMAL DOSAGE REGIMEN FOR APPROPRIATE TRAVEL VACCINES

Disease	Days Prior to Journey						
	35	28	26	24	21	14	7
Cholera	●						●
Typhoid Oral		●	●	●			
Typhoid Injectable	●						●
Meningitis	●						
Yellow Fever	●						
Japanese Encphalitis	●				●		●
Hepatitis A							●
Tetanus Diphtheria Poliomyelitis	● ● ●						
Malaria						●	●

Table 3

RAPID DOSAGE REGIMEN FOR APPROPRIATE TRAVEL VACCINES

Disease	Days Prior to Journey						
	14	7					
Cholera	●	●					
Typhoid	●	●					
Meningitis	●						
Yellow Fever	●						
Hepatitis A		●					
Tetanus Diphtheria Poliomyelitis	● ● ●						
Malaria	●	●					

FLUID BED DRYERS

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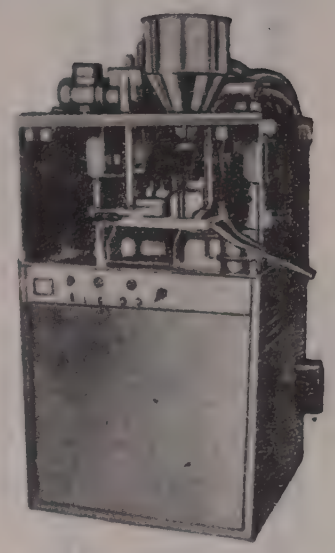

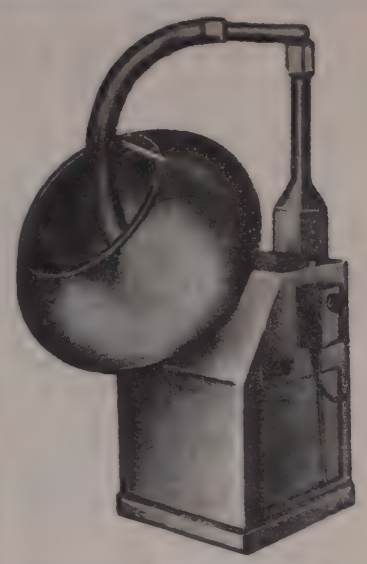

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- Improves functions of: Kidneys, Heart, Liver & Lungs.
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- ⋆ **Cardiac:** Mild to moderate High B.P congestive heart failure.
- ⋆ **Pulmonary congestion**

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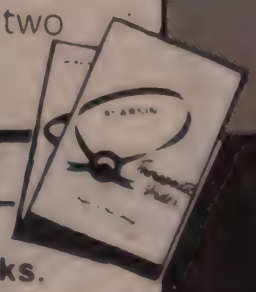

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NEW PHARMACEUTICAL PRODUCTS

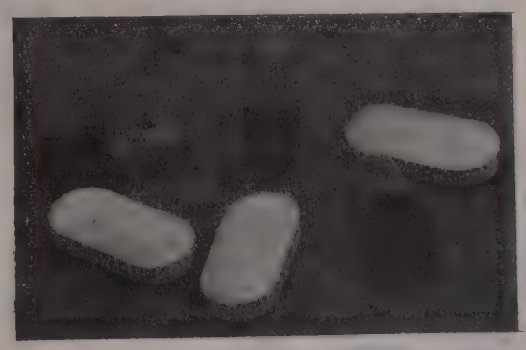
KEFLOXIN (Stancare)

Description: Stancare- A division of Ranbaxy Laboratories have announced the introduction of a new antibiotic Cefadroxil, under the brand name of *Kefloxin* in the form of capsules, tablets and suspension. Each capsule of the new product contains Cefadroxil USP equivalent to 500 mg of anhydrous Cefadroxil. Each tablet contains 1 gm. and each 5 ml. reconstituted suspension contains 125mg of anhydrous Cefadroxil.

Action & Uses: *Kefloxin* is an analogue of Cephalexin and has superior activity than existing oral cephalosporins against Gram-Negative and Gram-Positive organisms like Beta-hemolytic streptococci, Strep. pneumoniae, Strep. viridans and Staph.aureus including coogulase-positive and penicillinase - producing strains. (Gram Positive) E. coli, Proteus mirabilis, K. Penumoniae and H. influenzae. (Gram-Negative) *Kefloxin* is well absorbed from the gastro-intestinal tract and concentrations in the plasma and urine are more sustained than with cephalexin. *Kefloxin* is indicated for the treatment of Urinary tract infections, Skin and skin structure infections, Pharyngitis and tonsillitis caused by group A betahemolytic streptococci, Lover respiratory tract infections, Bone and Joint infections, caused by susceptible bacteria.

Contraindications & Precautions: History of allergy to cephalosporin group of antibiotics is a contraindication for the use of *Kefloxin*. The drug should be used with caution in patients with impaired renal function. Prolonged use of Cefadroxil may result in the over growth of non-susceptible organisms, which should be taken care of.

Dosage: *Kefloxin* is administered by mouth in the treatment of susceptible infections including those of the respiratory and urinary tracts. The



usual daily dose of the preparation is 1 to 2 gm. given as a single dose or in 2 divided doses. Recommended daily dosage for children is 30 mg/Kg/day in divided doses every 12 hours.

Supply: *Kefloxin* is supplied in strips of 6 capsules, strips of 4 tablets and Bottle of 40 ml. suspension.

Suppliers: M/s. Stancare - A Division of Ranbaxy Laboratories, New Delhi - 110 019.

TRICAINE-MPS (Searle)

Description: A new product for quick relief from pain and burning sensation in upper gastro-intestinal disorders containing ant-acids has been introduced by Searle under the brand name of *Tricaine-MPS* in the form of gel. Each 5 ml. of the gel contains Oxethazaine 10 mg., Simethicone(MPS) IP 125mg., Aluminium Hydroxide gel IP equivalent to 300 mg of dried Aluminium Hydroxide gel and Magnesium Hydroxide NF 150 mg.

Action & Uses: *Tricaine-MPS* besides antacids like Aluminium Hydroxide and Magnesium Hydroxide contains Oxethazaine which is a surface anaesthetic of the amide type, stated to have a prolonged action after a somewhat slow onset and is poorly absorbed from mucous membranes. It is administered by mouth in conjunction with antacids for the symptomatic relief of oesophagitis. Simethicone–an ingredient of *Tricaine-MPS* is a defoaming agent. thus the preparation helps in the relief of pain for the patients having oesophagitis of any etiology, peptic oesophagitis with or without hiatus hernia, radiation oesophagitis, gastritis, peptic ulcer, heartburn of pregnancy etc.

Contraindications & Precautions: *Tricaine-MPS* should not be given to a patient suffering from hypochlorhydria, anacidity and pyloric stenosis. It should be given with caution in renal insufficiency and low phosphorous diet. It may reduce absorption of tetracycline and may cause constipation.

Dosage: Recommended dose of *Tricaine-MPS* is one to two 5ml. spoonfuls three to four times daily.

Supply: *Tricaine-MPS* is supplied in bottle packs of 60 ml.

Suppliers: M/s. Searle India Ltd., Bombay - 400 025.

ORIPHEX (Alidac)

Description: *Oriphex* brand of Cephalexin has been introduced by Alidac Genetics and Pharmaceuticals in the form of capsules and dry syrup. Each capsule of the new preparation contains 250

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mg. and 500 mg., Cephalexin IP. and each 5 ml. of syrup contains 125 mg. of Cephalexin IP.

Action & Uses: *Oriphex* is bactericidal and has antimicrobial activity similar to that of cephaloridine or cephalothin against both Gram-positive and Gram-negative organisms. Cephalexin is almost completely absorbed from

the gastrointestinal tract and produces peak plasma concentrations about 1 hour after administration. *Oriphex*, a cephalosporin antibiotic, is administered by mouth for the treatment of infections of the respiratory and urinary tracts and other infections due to sensitive organisms. For severe infections treatment with parenteral cephalosporins is to be preferred. *Oriphex* is not destroyed by gastric acid but absorption may be delayed by food in the stomach or small intestine.

Dose: The usual dose of *Oriphex* is 250 to 500 mg. every six hours; in severe or deep-seated infections the dose can be increased to 3 to 6 gms. daily but when high doses are required the use of a parenteral cephalosporin should be considered. Infants and children may be given 25 to 100 mg. per kg. bodyweight daily in divided doses to a maximum of 4 gm. daily. In patients with impaired kidney function smaller doses should be employed.

Supply: *Oriphex* is supplied in strip packings of 24 X 4 capsules (250 mg. and 500 mg.) and dry syrup in bottles of 50 ml.

Suppliers: M/s. Alidac Genetics & Pharmaceuticals, Ahmedabad - 380 008.

BUFEX-PLUS (CFL Pharmaceuticals)

Description: A combination of Ibuprofen and Paracetamol has been announced by CFL Pharmaceuticals Ltd. under the brand name of *Bufex-Plus* tablets. Each tablet of the new preparation contains Ibuprofen 400 mg. and Paracetamol 500 mg.

Action & Uses: *Bufex-Plus* is a preparation which contains two well known analgesics, Ibuprofen and Paracetamol. The combination acts on pain pathways at the periphery and spinal relays to diminish transmission of pain sensation and is said to prevent prostaglandin biosynthesis to arrest both pain and inflammation. It is claimed that analgesic and anti-inflammatory activities are potentiated when Paracetamol is combined with Ibuprofen. *Bufex-Plus* fulfils this therapeutic need. It provides quick symptomatic relief from pain in soft tissue non-articular rheumatism, like myositis, fibrositis, teno-synovitis etc.

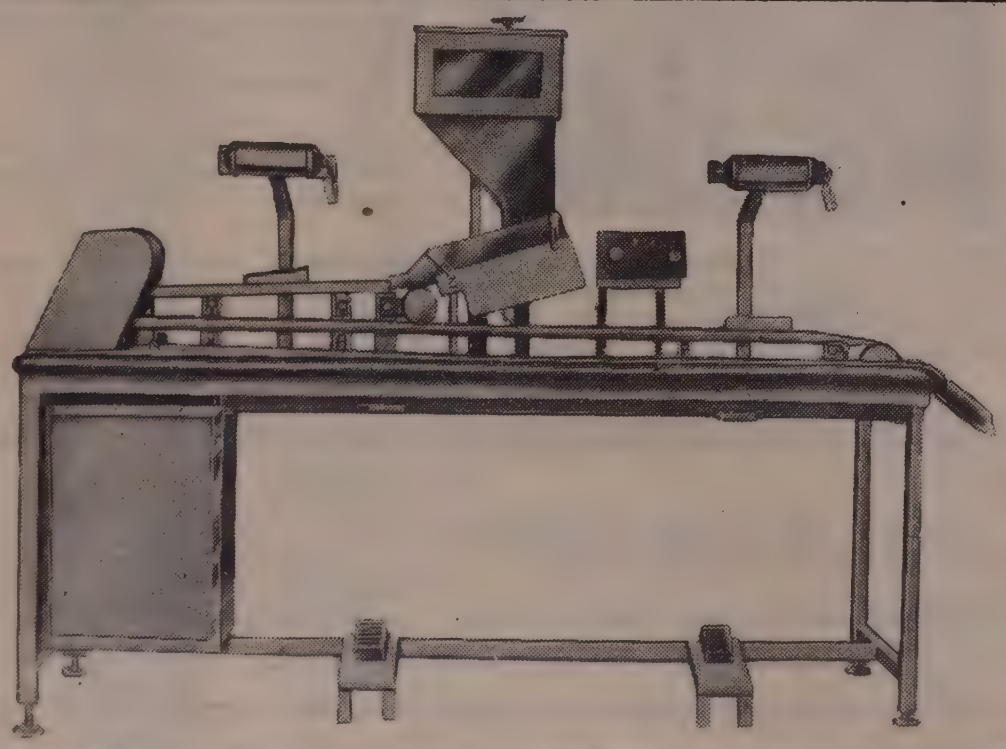
The preparation can be given in traumatic injuries due to accidents, sports injuries, sprains, strains, fractures and dislocations. It also can be given for pain in surgical trauma, infective inflammations, dental pain, dysmenorrhoea, acute exacerbation of rheumatoid or the similar inflammatory arthropathies, degenerative musculoskeletal disorders and miscellaneous aches and pains like headache, bodyache, myalgia, sinusitis headache, fever-flu syndrome etc.

Precautions & Contraindications: *Bufex-Plus* is to be used with caution in patients with a history of impaired function of eye, liver, kidney, heart or bone marrow. It should not be used in presence of peptic ulcer, moderate to severe liver, kidney or bone marrow impairment, hypersensitivity to the drug, Asthma and pregnancy.

Dosage: Recommended dose of *Bufex-Plus* is one tablet 6 to 8 hourly; children should be given half tablet 8 hourly. The drug should be taken after meals.

Supply: *Bufex-Plus* tablets are supplied in strip packings of 10 tablets.

Suppliers: M/s. CFL Pharmaceuticals, Bombay - 400 021.



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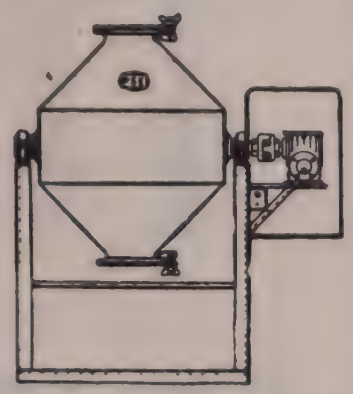

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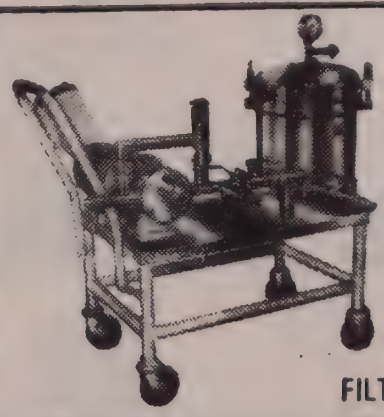

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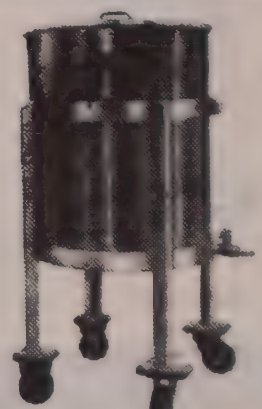

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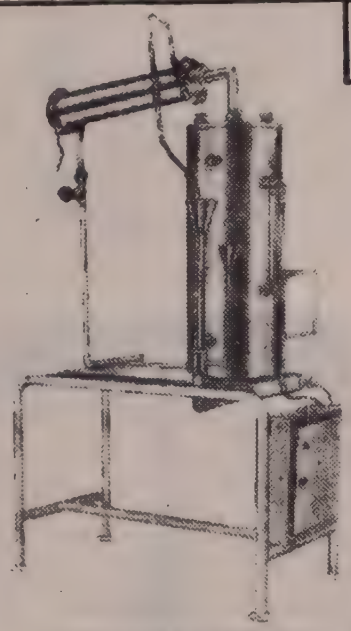

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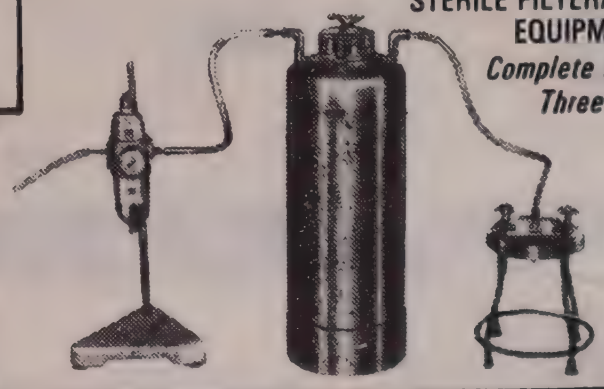

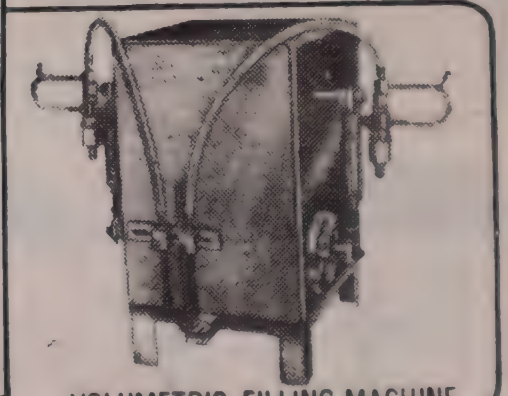

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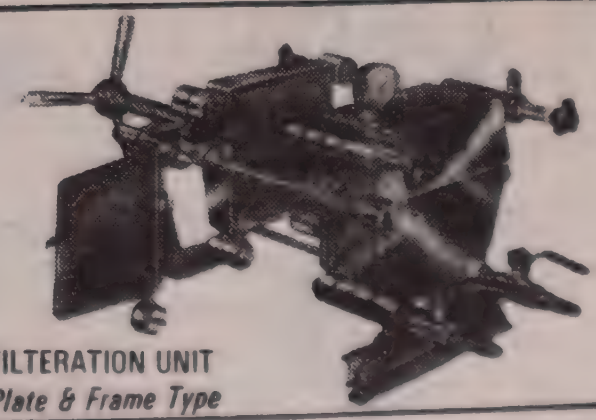

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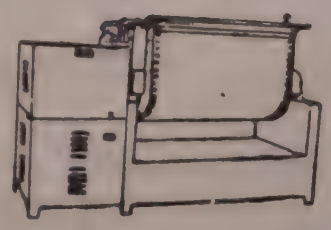

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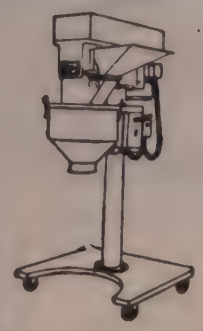

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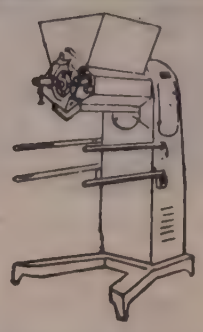

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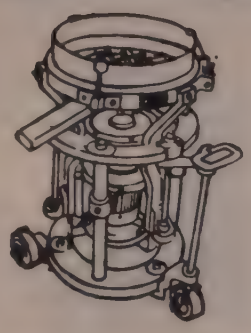

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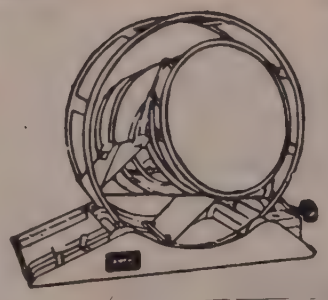

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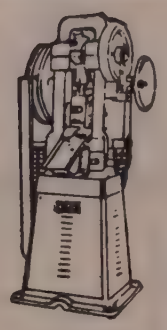

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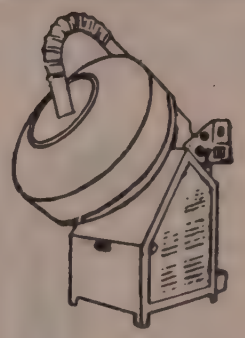

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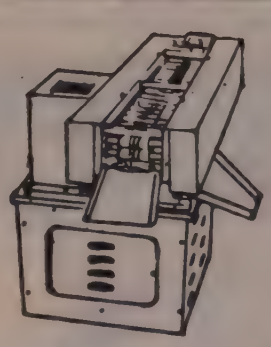

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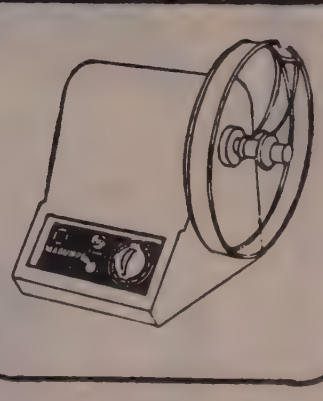

TABLET HARDNESS TESTER

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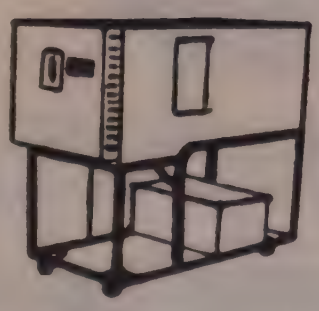

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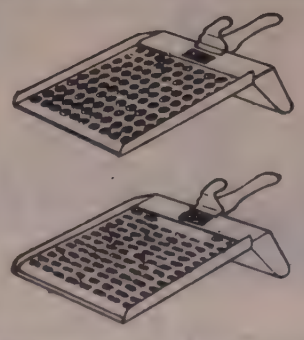

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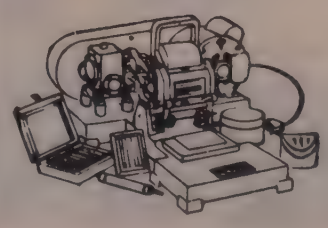

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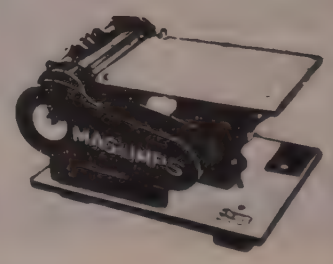

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BOOK REVIEWS

About Your High Blood Pressure Medicines: (3rd Edition). Published by The United States Pharmacopoeial Convention, Inc., 12601, Twinbrook Parkway, Rockville, MD-20852 (USA). Pages: 352. Price $ 6.95.

United States Pharmacopoeial Convention, Inc. produces many books for the use of pharmacists to up-date their knowledge and keep them fully informed about the health needs of the patients. In this connection the USP Convention has announced the publication of the completely updated and expanded 3rd edition of *About Your High Blood Pressure Medicines*, a lay language guide devoted to drugs used in the treatment of hypertension and other information specific to the condition.

The book provides profiles of the medicines most frequently prescribed for hypertension, including thiazide diuretics, beta-blockers, and others. Each profile details the brand and generic names, the proper use of the medicine, possible side effects, drug and food interaction, precautions storage directions, and information that should be considered before the drug is taken. The book is indexed by brand and generic names for easy reference.

A special introductory chapter includes a general explanation about high blood pressure and the influence of diet, exercise, etc. It also discusses the importance of patient participation in treatment and common misconceptions about high blood pressure. A "medication calender" is included as an easy-to-use chart for recording daily medication doses. A wallet diary is provided for the patient to list his or her physician's name appointment dates, and prescribed medicines.

The present 3rd edition of the book is produced in a new pocketbook size and new page format with larger, easy-to- read type make it easier than ever for consumers to access the same information that health care professionals have come to trust in the *USP-DI, Advice for the Patient*, US national database for drug information and patient education.

The book will be useful to the pharmacists, physicians and the patients suffering from high blood pressure.

Pharmaceutical Chemistry I. By Dr. N.C. Chaudhary. Published by M/s. Vallabh Prakashan, SU - 221, Pritam Pura, Delhi - 110 034. Pages: 80. Price: Rs. 18.00.

Many books are being published in the country on the subject of inorganic pharmaceutical chemistry meant for both degree and diploma students undergoing pharmacy education and training. The book under review has been written in accordance with the syllabus and guidelines on the subject of Pharmaceutical Chemistry I for the diploma course in Pharmacy as prescribed by the Pharmacy Council of India. The course content for Pharmaceutical Chemistry I is to be covered in only 25 theory lectures as mentioned in the Education Regulations of 1981 stipulated by Pharmacy Council of India. This book is meant exclusively for the diploma students undergoing pharmacy studies.

The book will be useful for the students of diploma pharmacy and the teachers, as it can serve as a text book.

Laws and Policies Affecting Adolescent Health: By John M. Paxman and Ruth Jane Zuckerman. Published by World Health Organisation, 1211, Geneva 27 (Switzerland). Pages: 300. Price: Sw. fr. 49.00.

The designation of 1985 as International Youth Year served to focus attention on the specific needs and aspirations of young people. This book presents the results of a comparative survey of how legislation affects the delivery of health care services to young people throughout the world; it describes approaches representative of current practices and assesses the trends in law and policy apparent on a global scale. A wide range of topics is covered, including sexual and reproductive health care, treatment of drug abuse, mental health care, and care for the disabled. The information is presented in a simple and straightforward manner so as to be easily understandable by administrators and policy-makers without a legal background.

This book is about that part of life known as youth. This is taken as covering the 10-24 years age group which accounts for nearly a third of the earth's population; more than 75% of these young people live in the developing world. Although the transition between adolescence and adulthood has certain clearly defined characteristics, neither the process nor the problems lend themselves readily to generalization; they are highly individualized, as is the effect on them of external influences. WHO document says: "For many adolescents and for some youth, their developmental health and social problems are closely entwined with those of their families, peer groups and local communities".

It is thought that one of the common desires of adolescents is to have realistic opportunities and reasonable life experiences, despite the fact that they live in vastly differing situations and an increasingly stressful world. Though health concerns usually rank low on the list of immediate priorities of most young people, such concerns are legitimate and important, and in many instances from an integral part of general adolescent experience.

The major health-related problems of adolescents are wide-ranging, and have been described by WHO as including the following:

"Socioeconomic deprivation and disadvantage; unemployment and underemployment; malnutrition;rural/urban migration; alcohol abuse and dependence; drug abuse and dependence; smoking; accidents and risk-taking behaviour suicide; sexual and reproductive health problems; mental dis-

orders; and mental retardation and other handicaps".

The present study under review focuses on some of these health-related, has its roots first of all in the recommendation made some years ago by a WHO Expert Committee, in a report entitled Health needs of adolescents that the legal and policy aspects of adolescent health care be explored, and that legislation be used to facilitate "more and better" health services. Then, in 1979, the United Nations, in General Assembly Resolution designated 1985 as International Youth Year. Among the youth oriented activities advocated in the resolution were those that would lead to the development of "comprehensive measures for intersectoral community-based health care".

On a global scale, adolescent health care issues continue to be neglected, possibly for two reasons–those who provided health care fail to recognize the special needs of adolescents and adolescents themselves tend not to utilize the services that are available.

This study looks at the way laws and policies throughout the world affect health care programmes for young people. It touches on what are perceived to be their major health problems, from sexual and reproductive to occupational, from mental illness to drug and alcohol abuse, from handicaps to accidents. It therefore aims to be "suggestive", in the sense that it will attempt to analyse the current situation and to suggest an array of legal and policy approaches that may be adopted in attempting to provide health care to adolescents.

A cautionary note is in order here. There is a danger in preparing a study of this kind, namely that of appearing to glance rapidly at a number of the world's legal systems with being aware of the basic differences, substantive and procedural, as well as philosophical, that exist between them. It is quite possible that a legal approach that seems perfectly adequate in one setting will be wholly inappropriate in another for any number of reasons, not the least of which that constitutional transcended. For example, the importance given to case law in the common law system may have little relevance in other legal systems where legal codes take precedence.

Equally, it may be unwise, indeed impossible, to adopt wholesale any of the legal approaches discussed in these pages. While it is expected that change in one country may prompt changes in others, experience indicates that it serves little purpose merely to copy a given law or regulation, especially where circumstances in the countries concerned differ widely. Nevertheless, the basic idea underlying a change in legislation may be widely applicable. The key is to adapt the approach so that it is woven comfortably into the local fabric. In this way, the change will become more than a mere academic exercise.

If there is a lesson to be learned from this study it is that there is no single legal model that can serve as an answer to all the legal and policy problems described here. Indeed, the world "model" is perhaps itself an unwise choice as it has come to be thought of as synonymous with "ideal". Many alternative legal and policy approaches exist, each of which can probably provide solutions, but the adoption of any particular one will depend on the nature and context of the legal and policy problem involved. Hence, what has been attempted throughout these pages is a description of as many alternative legal and policy approaches and solutions and solutions as can be found. It is the general approaches that recommend themselves, not the details of the legislation or regulation these must be worked out at the national level.

In short, this book is designed to inform the reader, in a general way, about what law and policy have to say about adolescent health care, to look briefly at the ways in which impose constraints on the development of adolescent health care programmes, to explore the various approaches that have been adopted around the world to eliminate, overcome, or avoid such constraints, and to examine how law and policy have been utilized to ensure greater access by adolescents to health care. The book essentially views law and policy as facilitating rather than inhibiting such access. Finally, it should be seen as a source book for ideas rather than a definitive treatise.

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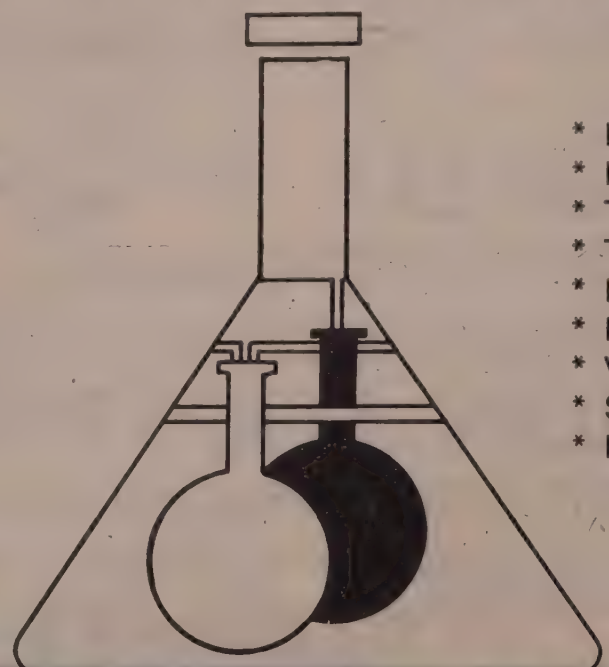

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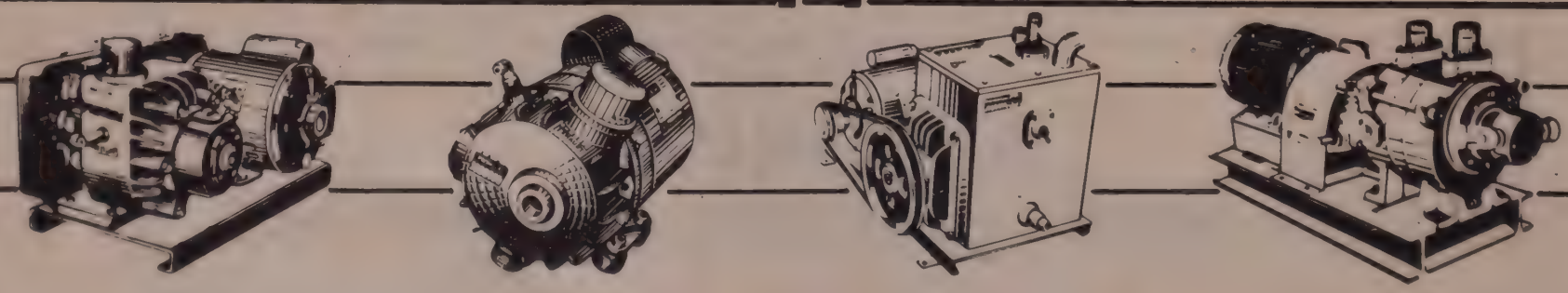

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Drug Prices Frozen, Fresh Licence Issue Halted Move To Force Cos. To Pay Up Dues

BOMBAY: The Union government has halted approvals for price increases and issue of industrial and expansion licences, as well as product registrations till the pharmaceutical industry pays up dues amounting to Rs. 22.63 crore into the durg prices equalisation account (DPEA).

The government's decision, which was conveyed to industry recently, has brought the operations of pharmaceutical units grinding to a halt. The decision is oral as a written order clubbing payment of dues into the DPEA with other issues could be challenged in courts. Simultaneously, the ministry has set up an internal committee to hold talks with drug units on payment of outstandings. The issue has been simmering for the past few years and is now on the boil with the government keen on full payment.

Twenty-six companies have to pay Rs. 22.63 crore for over charging. Some units have partly paid their dues while contesting the rest. Others have not even made token payments. The current decision is forcing them to change their minds, though payments will be under protest as companies contend that the government will have to pay back to compensate losses.

The DPEA was a part of the 1979 drug policy and dropped when it was revised in 1989 as it was cumbersome. However, the government reserves the right to get back payments on old counts.

The companies owe about Rs. 8.50 crore for overcharging users of rifampicin between 1979 and 1984. World bulk drug quotations of rifampicin had dropped during this period which helped units to formulate it at cheaper prices. At that time, the government had refused to cut formulation prices. However, bulk drug prices shot up between 1984 and 1986 wiping out the profits realised on formulations and the industry contends that losses cross out earlier gains. However, the government is not convinced by this argument.

The companies involved (amounts assessed in brackets) are: Biochem Pharma (Rs. 68.16 lakh), Lyka Labs. (Rs. 85.04 lakh), Mirco Labs. (Rs. 2.24 lakh), Themis Chemicals (Rs. 36.31 lakh), Alembic Chemicals (Rs. 38.73 Lakh), Bombay Drug House (Rs. 1.73 lakh), Pharmed (Rs. 68 lakh), Dolphin (Rs. 18.11 lakh), Pharmaceuticals & Chemicals (Rs. 87.99 lakh), Cadila (Rs. 76.52 lakh), Lupin Laboratories (Rs. 2.15 crore), Ethico (Rs. 1.40 crore) and Franco-Indian Pharma (Rs. 11.02 lakh). Of them, only Franco-Indian Pharma has paid Rs. 43,000.

Major pharmaceutical units have also defaulted, They are: Astra IDL (Rs. 24.11 lakh), Sarabhai (Rs. 4.14 lakh), Wallace (Rs. 2.82 lakh), German Remedies (Rs. 59.95 lakh), Fulford (Rs. 194.62 lakh), Cyanamid (Rs. 3.89 crore), Hoechst (Rs. 4.58 crore), Wyeth (Rs. 1.33 crore), Pfizer (Rs. 48.21 lakh). Of them Fulford has paid Rs. 50 lakh, Cyanamid Rs. 50 lakh, Hoechst Rs. 3 crore, Wyeth Rs. 25 lakh and Pfizer Rs. 10 lakh.

Four other units who are not members of drug associations are: Albert David (Rs. 3.91) lakh), Ranbaxy (Rs. 47.78 lakh), Geoffrey Manners (Rs. 38.37 lakh), and Ethnor (Rs. 8.15 lakh). Only Ethnor has paid Rs. 8 lakh.

Industry contends that the dues have been calculated arbitrarily with the government refusing to divulgebulk drug prices it has taken into account to work out formulation prices. Manufacturers have also been unable to make suitable provisions in their accounts and the tax authorities are generally unwilling to allow provision for a "potential" claim under DPEA as a tax deductible expense.

They also feel surtax, excise duty, sales tax and other applicable levies have already been paid and retroactive demands could lead to losses. The government is not convinced, though it will have to make some effort to stick to its demand for Rs. 22.63 crore.

Drug Industry Held To Ransom

MADRAS: In an unprecedented move the Department of Chemicals and Petrochemicals is allegedly holding the entire drug industry to ransom because of the failure of some two dozen companies to deposit their dues in the drugs prices equalisation account (DPEA).

Some of the concerned officials have let it be known to drug producers that their applications for price revision, industrial licences, capacity registration and so on would not be considered so long as DPEA dues remained outstanding.

Stunned by the Government's refusal to consider price revision applications of even those producers who have nothing to do with DPEA, some aggrieved company officials naturally made inquiries about the Government's objective in penalising the entire industry for the alleged fault of a few units.

Government officials at various levels either gave evasive replies to such inquiries or asked questionners to see "higher authorities". Some producers, who are not in the know of these developments, refuse to be-

lieve that the government can be so arbitrary and unfair. As, however, there is nothing in black and white, aggrieved producers cannot even contemplate an approach to the judiciary for the redressal of their grievances. Moreover, even under the law the Government is free to take its own time to consider price revision applications.

The Government's attempt to use DPEA arrears for delaying price revision has puzzled the industry for two reasons. First, the Government itself has discontinued DPEA in the new drug policy announced in December 1986. The policy itself has conceded that "DPEA was set up essentially to encourage domestic production of bulk drugs through a system of retention pricing. However, in actual practice the operation of DPEA is giving rise to intractable administrative problems".

And second, a committee set up by the Government is already looking into the so-called defaulters' representations against the demand made by the Government. Some companies have partly cleared their DPEA arrears and the balance is under discussion between the two sides.

A major producers, who prefers to remain anonymous, feels that as price revision is not related to DPEA the Government is using a non-issue to delay politically inconvenient price revision in an election year.

Some other producers suspect that the Government is using these unfair and indefensible tactics to make the industry fall in line with the "wishes of political bosses".

Meanwhile, the industry is eagerly awaiting the Government's response to its representation in this regard.

Drug Co. Dues, Govt. Insists On 10% Initial Payment

BOMBAY: The government has agreed to allow capacity expansion by drug companies provided they pay up 10 per cent of the total dues into the drug prices equalisation account immediately.

At a meeting the government officials clarified that the total dues as worked out by the ministry stands at Rs. 22.63 crore. Dismissing pleas for initial payments below the 10 per cent mark, the government told industry representatives that further payments should preferably be in equal instalments of 20 per cent over a period to be decided by the ministry later.

The government directive has put the industry in a fix as the Supreme Court has ruled out bringing the issue of drug pricing into courts. It can at best dispute the basis of calculating the dues by the internal committee set up by the government for this purpose.

An analysis of DPEA claims on drug companies shows that foreign-owned Indian drug companies have started paying dues with Hoechst already clearing Rs. 3 crore of its Rs 4.58 crore dues. The balance will be paid up shortly.

Of the total Rs. 22.63 crore dues, around Rs. 8.50 crore has been assessed on fully-owned Indian drug companies and that too, on Rifampicin manufacture. These companies seemed to have over charged users of Rifampicin between 1979 and 1984 when world quotations of bulk drug imports fell, while that of formulations were not cut pro rata by government.

2 Bulk Drugs Prices Raised

BOMBAY: The government has hiked the prices of two important bulk drugs, namely rifampicin and ibuprofen, it is learnt.

The price of rifampicin is now fixed at Rs. 3500 a kg against its earlier price of Rs. 2500 a kg. The price of ibuprofen is revised to Rs. 500 a kg from Rs. 400 a kg.

"The Economic Times" in its issue dated May 9 last had reported that the government was considering a hike in the prices of both the drugs.

Only eight months ago, the government had cut the price of rifampicin, a widely used anti-T.B. drug to Rs

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2500 a kg from Rs 3000. The price of ibuprofen was also reduced at that time to Rs. 400 a kg from Rs. 810 a kg.

The price revision of both the drugs were considered arbitrary and unrealistic by the drug units and a number of representations were made by the drug units against those price cuts.

The department of chemicals and petrochemicals had then asked the Bureau of Industrial Costs and Prices to investigate the actual costs of manufacture of these drugs and recommend new prices. With the upward revision of the prices of these two bulk drugs, the prices of formulations of these drugs, particularly that of rifampicin formulations, are also expected to go up shortly.

Drug Cos. Deposit Excess Amount In DPEA

NEW DELHI: The drugs and pharmaceutical companies which had overcharged consumers against the prices fixed by the Government in the Drug Prices Control Order (DPCO) 1979, have started depositing the excess amount due from them in the Drug Price Equalisation Account (DPEA).

As of July 15, 79 such companies have deposited an amount totalling Rs. 69 lakhs. These companies are other than those 10 pharmaceutical units which have moved the court against the Government directive. However, as the 79 firms have also made the payments under protest and certain reservations, a special committee set up by the Government has worked out an evaluation criterion for the norms of payment.

Disclosing this to members of the Consultative Committee attached to his Ministry, the Union Industry Minister, Mr. J. Vengala Rao, said that the special team was now calculating the amounts to be recovered from the erring units based on the evaluation criterion.

Mr. Rao told members that in respect of the 10 companies involved in cases in the Supreme Court, the special team has determined that the net total amount payable by four companies was Rs. 594.41 lakhs after taking into consideration the recommendations of the price review committee. Of this, an amount of Rs. 401 lakhs has already been paid by the companies for depositing in DPEA.

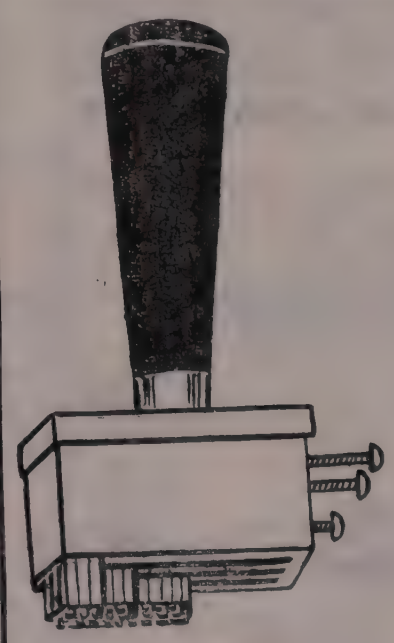
The amounts payable by the other six companies are being worked out and it is expected that recovery of the entire amount would be made from them soon, Mr. Rao said.

As for the fixation of prices under the new DPCO, the Minister said that out of the 112 bulk drugs, prices had been fixed for 54 and for another 35 it was under the process of finalisation. For the remaining 23 bulk drugs, prices continue to be those as fixed under the earlier DPCO.

Referring to the members' charges of overcharging by certain companies in the prices of bulk drugs, Mr. Rao said that whenever such cases came to the notice of the Department of Chemicals and Petrochemicals, the drug controllers in the State were informed. At times, the States have also been asked to take suitable remedial measures. He assured members that his Ministry was monitoring the prices of some of the important drugs.

Mr. Rao said that his Ministry was aware of 10 pharmaceutical units that have been overcharging in bulk drugs. Four companies were over charging in the prices of the bulk drug, theophylline. These are Luke Chemicals Pvt. Ltd., Pefco Industries Ltd., Trichem Lab. Limited and Bakul Aromatics and Chemicals Limited. Similarly, four other companies were overcharging in paracetamol. These are Shree Krishna Pharmaceuticals Ltd., A.P. Chemicals Ltd., Farmson Pharmaceutical Gujarat Pvt. Ltd. and Pharmson Analgesics (P) Ltd.

The other two companies, Syntholab Chemicals and Research Ltd. and Malladi Drugs and Pharmaceuceutical Ltd., were overcharging in the prices of chloramphenicol powder and ephedrine hydrochloride, respectively.



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Some members brought to the notice of the Minister the applications for expansion and setting up of units in areas which are already industrially overcrowded. Clearances to these units, they noted, would hamper the pollution control measures and result in becoming hazards to the environment. Mr. Rao said that the Government was fully aware of such situations. He assured members that pollution and enviromental factors were always kept in view while granting permission for setting up such industrial units.

Drug Units Project 8.8 p.c. Growth

BOMBAY: The drug industry hopes to maintain the 8.8 per cent growth in production of formulations that it achieved in the seventh plan during the next plan period. However, the industry estimate is in sharp contrast with the planning commission projection of 12.4 per cent growth rate for the pharmaceutical industry in the eighth plan.

The industry projection has been made in a paper prepared by a working group jointly constituted by the Organisation of Pharmaceutical Producers of India (OPPI) and Indian Drug Manufacturers' Association (IDMA). The planning commission circulated a background paper to the industry indicating Rs. 4,500 crore worth of formulations output during the eighth plan period. However, the planning commission has not quantified the bulk drug production to back this claim.

The experts of both the associations have shown in the prepared paper submitted to the secretary of the department of chemicals and petrochemicals, Mr. M. S. Gill, that on the basis of 8.8. per cent growth rate, per capita consumption per annum will increase from Rs 52 in 1989-90 to Rs. 71.3 in 1994-95, at 1979 prices and at the estimated 1989 prices, respectively.

The OPPI-IDMA-Joint paper has also estimated that to achieve a production level of Rs. 6,610 crore in 1994-95, a total investment of Rs. 2,200 crore will be required, against Rs. 750 crore at present. There is, thus a shortfall of Rs. 1,450 crore. This will be further reduced if the idle capacity estimated at one-third of the total is taken into account and assuming that full utilisation of the installed capacity will be made during the eighth plan period. The additional investment will then have to be Rs. 1,200 crore.

Here again, the planning commission projection conflicts with the industry estimates. The plan body's background paper projects an actual additional investment of Rs. 350 crore as there is enough unutilised capacity in the industry.

This is based on the assumption that an additional Rs. 700 crore will be required to reach a total investment of Rs. 1,500 crore during the eighth plan period to achieve a formulations production level of Rs. 4,500 crore on the basis of a 1:3 investment-output ratio.

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Nobel Calling With a Different Face

NEW DELHI: India has a high infant mortality rate, with estimates varying from 105-220 deaths for 1,000 live births. To fight this high mortality rate among children and to improve the health status of pregnant women the National Technology Mission on Immunisation was set up.

The Mission sets out to cover in a phased manner a target population of infants (under one year of age) and pregnant women with immunisation against six vaccine preventable diseases of children.

Drawing its inspiration from the not very successful Extented Programme of Immunisation (EPI) and the Universal Immunisation Programme (UIP), the Technology Mission of Immunisation aims at covering 90 per cent pregnant women and 85 per cent infants by 1990. Its objective is reduction of morbidity and mortality due to diptheria, whooping cough, tetanus, poliomyletis, tuberculosis and measles among infants and reduce mortality due to tetanus amongst pregnant women. The Mission also hopes to achieve self sufficiency in vaccine production by 1990.

Although one of the obstacles of the Mission has been stated as reduction in mortality rate due to tetanus amongst pregnant women, official figures show that this is not an important cause of death among them. The Mission is therefore left with the twin objective of

reducting infant mortality and attain self sufficiency in vaccine production.

According to Mr. P.K. Meherotra, the Director of the Technology Mission on Immunisation, the EPI was basically formed to eradicate small-pox which it did satisfactorily. The progamme provided an encouragement to tackle some more communicable diseases. At that time, howeveer, the approach was limited. Nor was the programme without any problems. Equipment was not provided for and the staff was not properly trained. The major shortcoming was inadequate transporation facilities to take the vaccine to the immunisation centres.

Realising the need for proper management to attain good results, the Technology Mission is better organised. A more methodical approach although, right from the higher level, has been worked out.

Success often depends much on the inputs invested. The Government has provided an outlay of Rs. 240 crores for this programme till 1990.

The Technology Mission with an outlay of Rs. 240 crores plans to provide health services through the existing health care centres, whose dismal performance has been a target of allround criticism. A primary health care centre serves a population of 100,000 or more. Many posts, especially of female health functionaries, are lying vacant. There is only one doctor for a population of 12,500 and one hospital for bed 9,000 in Maharashtra to 104,000 in Bihar.

The Mission faces no paucity of funds as it has at its disposal 55 per cent of the amount allotted for control of all communicable diseases in the Seventh Plan. But it has before it the gigantic task of improving health services in the country especially in the rural areas. It is confident of achieving its targets within the allotted time frame.

According to Mr. Meherotra a lot has been done on the vaccine production front. Efforts are under way for totally indigenising the production of vaccine. In vaccines, preservation plays a very important role and for this the Mission has not only identified the type of cold chain equipment needed but also worked out the technical details for it. In fact it has come up with an airtight equipment which has attained considerable success.

However, Mr Meherotra does not find the overall development of health facilities in the states to be uniform. While in some states the health centres are producing good results in others they are quite backward

The cold chain equipment produced by the Mission is capable of withstanding power failures for as long as 18 hours. But in some states the power supply is so erratic that breakdowns continue for about 48 hours, upsetting the whole programme.

The Mission Director holds the poor development of medical facilities in some states responsible for the tardy progress of immunisation at the national level.

On immunisation, a survey finds that the six diseases the Mission has taken up to eradicate accounts for just 10-12 per cent of infant deaths. About 60-90 per cent of the deaths, among children below five years of age are due to acute respiratory infection (ARI) and diarrhoea.

According to Mr. Meherotra the oral rehydration therapy (ORT) programme, which is in operation in all centres where the Mission is active, helps to fight diarrhoea. For treating ARI problems a separate scheme will be launched. However, going by past experience of launching of schemes by the Government one hopes it would be done with greater speed this time.

Immunisation is a noble cause but if the effort is not continuously maintained, the results can be disastrous. To quote Ms Sathyamala, former Editor of Medico-Friends Circle Bulletin, in a recent issue of the journal "Seminar", "a spectacular immunisation effort, if not well followed through, can produce an equally spectacular epidemic. High immunisation levels achieved briefly only temporarily suppress the transmission of disease. New borns can then accumulate as susceptible children until disease transmission again becomes easy. It is at this point that an epidemic may explode. This

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was the case in Singanikuppam village in the Tindivanam taluk of Tamil Nadu, where a severe outbreak of measles with a high fatality rate occurred two years after a successful immunisation programme for measles".

An equally daunting task the Mission faces is on sterilisation. Without care for sterilisation, mass injectible vaccination programme can lead to the outbreak of Hepatitis-B, which is present in more than four per cent of the population. A study, infact, shows that the incidence of Serum Hepatitis in post vaccinated children has been as high as 10-15 per cent.

Asked to comment on it, the Director parried the issue but later said that sterilisation had not played an important role in the earlier programmes. The Mission was working for providing by 1989-90 an adequate supply of syringes and needles so that a freshly sterilised needle can be used on each occasion.

A major obstacle the Mission will have to overcome is low health services in the country. According to the "Seminar" the per capita per year health expenditure in rural areas is approximately 20 paise. The women health workers who form the back-bone of mother and child services have 180 days per year for regular visits to the village and during that time have to perform 11 major tasks divided into 41 sub-tasks, giving them barely 20 minutes per house per year!

To get over this problem the women health workers organise immunisation camps, in their districts, where about 40-50 people conglomerate. This saves a lot of time and the work gets done in two to three hours' time. The worker then also finds time to provide the village folk with information on child care and other related matters. However, the need to step up the per capita per health expenditure in rural areas remains.

USSR Buys Rs. 30 cr. Medicines

NEW DELHI: The Soviet Union has bought Rs. 30 crores worth of medicines and medical raw materials from India, Mr M.S. Gill, secretary, department of chemicals and petrochemicals, has said, reports PTI.

Moscow recently had an exhibition-cum-seminar, "USSR India co-operation in medical industry and development of pharmaceuticals", sponsored by the USSR ministry of the medical and microbiological industry, the Indo-Soviet Chamber of Commerce and Industry, and the USSR Chamber of Commerce and Industry, an APN report from Moscow said.

DCW To Set Up Iodised Salt Unit

BOMBAY: DCW Ltd., a city-based chemical company, is setting up the country's first unit to manufacture free-flowing iodised salt conforming to international standards. The company plans to export 25 per cent of the proposed annual capacity of one lakh tonne.

India still does not produce free flowing salt (so called because it will not absorb moisture, lump and choke the salt shaker) which is the norm not only in developed countries of the west, but also in neighbouring countries like Indonesia and Thailand. It will not form lumps even when kept open during the monsoon season.

The fully automated plant will be set up in Palghar near Bombay at a cost of Rs. 7.25 crores. The key equipment will be imported from Switzerland. Crude salt, purchased from small-scale farmers, will be washed, refined and dried to 0.2 per cent moisture level. Tata Salt, the popular brand, has around five per cent moisture content.

The plant, scheduled to go on stream in January 1990; will produce various types of salt like table salt, cooking salt and pharmaceutical grade material. It will be a premium product aimed at the discerning customer but not beyond the reach of the middle class, according to a company spokesman. As a prelude to launching the new product, DCW Home Products Ltd has begun marketing "Marvo" brand free flowing salt which has been well received by five star hotels and restaurants in the city.

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Numerous small-scale units produce iodised salt. Tata Salt is the only branded iodised salt with a countrywide market. Salt is a byproduct of the Tata Chemicls' desalination plant in Mithapur, set up to produce water from brine to feed its soda ash plant. The company converted this byproduct into a successful, national brand. The Mithapur plant has a capacity to produce 2.5 lakh tonnes a year.

The Salt Department has been distributing iodised salt in the tribal belts in Himalayan foothills as part of the Government's programme to prevent goitre. Acute iodine deficiency leads to goitre but the fact that small deficiencies can retard mental development leading to "cretinism" is less well known. To prevent this, iodised salt is preferred in advanced countries like United States. China is one of the world's leading consumers of iodised salt.

Like "Jaag," the new detergent promoted by the company, salt will be marketed by the newly set up DCW Home Products Ltd., which is being promoted as a marketing company with a network of retailers and stockists backed by computer software to monitor sales.

Drug To Improve Heart Function Developed

BAREILLY: Indian scientists have developed a drug from the plant Terminalia arjuna, which they say lowers high cholesterol levels in blood, maintains the ratio of total cholesterol and high-density lipoproteins (HDL) and improves myocardial perfusion.

Experimental studies conducted at the Indian Veterinary Research Institute, Izzatnagar, have clearly demonstrated an improved cardiotonic effect of the drug 'cardiotone H' developed from Terminalia arjuna.

The drug helped to maintain the total cholesterol (TC) levels and the ratio TC/HDL-C. (high density lipoprotein—cholesterol) within the normal limits in experimental rabbits fed on cholesterol-rich diet. In addition, it showed marked perfusion (the pumping of a fluid through a tissue or organ by way of an artery) of blood vessels, indicating its direct role in revitalising the myocardium for combating coronoary occlusive conditions. IVRI researchers A K Bhargava and N P Bhalla said in a report.

Serum samples of rabbits fed cholesterol—rich diet and then administered withthe drug, showed a 21.5 per cent decrease in the blood TC levels, while the TC/HDL-C ratio was kept within normal limits. Other drugs, obtained from "neem" (Azadirachta indica) and methi (trigonella sp) failed to stabilise the ratio.

Coronary angiographies (the process of taking X-ray photographs of blood vessels by injecting the vessels with a substance opaque to the rays) revealed better mayocardial perfusion under the influence of cardiotone than under the influence of neem oil or methi.

The IVRI team found that when the coronary ligation—the surgical tying o f vessels or ducts with a cord or thread—was performed under the influence of cardiotone, it helped to regularise heart-beat and prevent tachycardia (excessive rapidity of the hearts action) and fibrilations (independent, spontaneous local twitching of muscle fibres).

The drug will also help provide cheaper and better treatment for heart diseases in animals, Preliminary trials in human volunteers have shown promosing results, the report said.

Tax Relief Urged For Promotion Of Family Planning

NEW DELHI: Assocham has sought a modification of the tax laws to enable the private corporate sector to promote family planning and allied social activities among employees as well as the community at large.

In a statement the association said companies have not been able to undertake such activities for two reasons firstly, expenditure on such activities is not

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vities is not allowed under the existing law and, secondly, companies contributing money to institutions conducting in family planning programmes cannot claim any tax deduction on such bona fide expenditure.

In a communication to the ministry of finance, Assocham has suggested that an assessee having income under the head 'profits and gains of business and profession' be allowed to claim a deduction of bona fide expenditure by way of contributions to institution engaged in the promotion of family planning and social welfare activities, provided the assessee furnishes a certificate from such a recognised association or institution to that effect.

Assocham has also urged the government to allow tax deduction on expenditure incurred by the company on promoting family planning among the general public.

SDR 87.2 m In IDA Credit For Family Planning In India

NEW DELHI: The International Development Association (IDA) will give India a credit of SDR 87.2 million and the World Bank a loan of $ 11.3 million for a family planning project, reports say.

The World Bank said the project aimed at slowing down birth rates in Andhra Pradesh, Madhya Pradesh and Uttar Pradesh.

More than 800,000 health workers and family planning personnel will receive training, the bank said recently.

The project involves for the first time practitioners of indigenous medicine to promote family welfare.

A bank release said India's family planning programme has grown steadily since 1980.

"But to be more effective in reducing birth and infant mortality rates the programme needs to be more accessible to those who require its services most, the release said.

The project will help resolve this problem by increasing the capacity of the state directorates of health and family welfare to monitor its programmes, makes sure its personnel are adequately trained and shift the emphasis of services towards younger families.

The project will also support the innovative effort of involving practitioners of indigenous medicine to promote family welfare, and modifications in management system to improve the quality of services.

The World Bank loan is for 20 years, including five years of grace, with a variable interest rate, currently 7.65 per cent, linked to the cost of the bank's borrowings It also carries an annual commitment charge of 0.75 per cent on the undisbursed balance.

The credit (loan) from IDA, the soft-loan window of the World Bank, is for 35 years, including 10 years of grace. It carries no interest but has an annual charge of 0.75 per cent on the disbursed balance and a variable charge of up to 0.5 per cent (currently zero per cent) on the undisbursed balance.

Chemexcil Target Surpassed

BOMBAY : The chemical, pharmaceutical and toiletry industries cannot double their export turnover in the new financial year unless fresh capabilities are created quickly.

This is the near-unanimous opinion of major exporters who, through the Basic Chemicals, Pharmaceuticals & Cosmetics Export Promotion Council (Chemexcil) has submitted a detailed list of machinery and equipment whose duty-free import will go a long way in boosting exports. Speedy import of second-hand plants and machinery has also been mooted.

Chemexcil has surpassed the 1988-89 target of Rs. 1200 crores. The year's export turnover amounted to Rs 1247 crores. The earlier target of Rs 900 crores was revised upwards to Rs 1200 crores during the course of the year in view of the favourable demand and the precarious balance of payments position.

The Council has now been assigned the challenging task of doubling the export turnover. (The above figures excludes earnings from raw naptha exports which accounted for Rs. 99 crores during the year).

The dyes and dye intermediates panel registered the biggest growth of 87.6 per cent. Exports touched Rs. 410.6 crores, compared to Rs. 213.9 crores during the previous year. This industry, which has the most potential, is not only saddled with old plant and machinery, but raw material constraints.

Basic drugs and finished pharmaceutical formulations came second, accounting for Rs. 400.16 crores. This excludes medicinal castor oil which accounted for another Rs. 76 crores. Formulation exports, on the downhill for several years, picked up momentum thanks mainly due to sizeable African orders.

Export of organic, inorganic and agrochemicals recorded a 62 per cent increase, touching almost Rs. 150 crores. Exports of soaps, detergents, cosmetics and toiletries netted Rs. 139.8 crores compared to Rs. 85.5 crores during the previous year.

The dramatic increase was mainly due to handsome Russian orders. The main exporters in this category are Hindustan Lever, Lakme, Tomco, Balsara and Godrej. It is reported that 23,000 tonnes of detergents

have been already booked for the new financial year, almost all of it from Soviet Union.

Exports of essential oils (ginger oil, sandalwood oil, lemongrass oil, jasmine, tuberose and miscellaneous oils) increased marginally to Rs. 17 crore during the year. Exports of crude drugs like opium, psyllium husk and seeds, senna seeds and pods, however, declined from Rs. 77 crores to Rs. 61 crores.

Another bugbear of the export trade is supply of intermediates at international prices. The scheme is already in operation, though exporters complain that public sector units, who have a near-monopoly of several basic chemicals, are not co-operating as they should.

India's Opium Stock Too High : US Study

NEW DELHI : A study carried out under the director of the House Foreign Affairs Committee describes India's controls over diversion of licitly grown opium to the illicit market as 'lax' and her opium stocks too high, and it raises the question whether India should be allowed to continue to have her present large share of the US licit market, PTI reports.

It, however, leaves that to be discretion of the government. The study also rejects Australia's contention that it is entitled to compete freely in the American market on free market principles and that the policy under which the US reserves 80 per cent of the US licit market to India and Turkey is a violation of Gatt principles.

The staff report reveals that there has been a "gentleman's agreement" historically under which producer countries did not manufacture finished drugs and the manufacturing countries did not produce licit opium. This understanding, it said, has been "dissipated over the years".

The US pharmaceutical industry is the largest single user of licit opium—one third of the world market i.e., some $ 15 million worth, valued at perhaps $ 300 million in finished drugs.

India the study notes, has produced opium for millennia. It is the only remaining supplier of licit opium to the US market which utilises opium gum method rather than the CPS method which makes diversion to heroin difficult (in the CPS or concentrated poppy straw method, developed by a Hungarian scientist in the thirties, opium poppies are not incised as in the gum method. Rather, the poppy capsule and the top part of the plant are cut off and then processed into a bulk intermediate product. The CPS method is cheaper because the crop can be harvested mechanically).

Because India does not use the CPS method, says the study, carried out by a team led by Mr. F. Marian Chambers, it requiries some 150,000 farmers who produce 600 metric tons of opium gum (60 metric tons of morphine equivalent).

This extensive involvement in the industry by Indian labourers in a desperately poor economy has mitigated against conversion from the opium gum method to the CPS process, the study added.

Notification On Needles, Syringes Welcomed

AHMEDABAD: The Union Ministry of Health and Family Welfare, has specified disposable hypodermic syringes, disposable hypodermic needles and disposable perfusion sets as "drugs" vide a recent notification, issued in consultation with the Drugs Technical Advisory Board.

This is intended to ensure hygienic and sterility parameters in the production of disposalbe needles, syringes and perfusion sets like drugs manufacturing. In other words, the notification is a clear indication that these items can be manufactured now only by units having drug manufacturing licence, as disposable needles and syringes are also specified as "drugs".

The Government should promptly implement the recent notification covering disposable syringes, needles and perfusion sets, under the definition of "drugs" to safeguard the health of teeming millions, according to the country's only pharmaceutical company making disposable syringes and needles viz Cadila Hospital Products Ltd.

Welcoming the notification, Mr. Indravadan Modi, Chairman of the company which has recently gone public said here although such a measure was overdue now at least consumser would be ensured of a product made under good manufacturing practices.

The disposable syringes which are at present made by a number of units in both organised and unorganised sectors, would now be subjected to strict tests and only those made under controlled environment, ensuring totally hygienic and sterility parameters, would pass these tests prescribed under the notification Mr. Modi said. This would also, help minimise the risk of infection, he added.

Mr. Modi, also suggested that while enforcing a strict control on the manufacture of disposable injection products in the country, the Government should set up extensive facilities for random sampling and testing of imported syringes and injection equipments.

The foreign makers of these equipment who have to comply with strict conditions for their home markets, might not be imposing the same standards for export products, he said.

Quoting from a leading medical magazine, Mr. Modi said thanks to our in-born preference for everything foreign whether good or bad, an imported syringes could be sold at a much higher price than those

made in the country. Against a total projected demand of 100 million syrings 16 existing units and 12 units in pipeline can produce 570 million syringes. Their quality is internationally acclaimed. On the other hand, the imported syringes may not be subjected to exhaustive quality control in India, as adequate testing facilities are not available to test every imported consignment of syringes and needles.

Referring to the increased danger of AIDS, hepatitis and similar ailments, Mr. Modi, said the new measure would be definitely help preventing the spread of contagenous diseases in our country.

Official Review Of Drug Production

NEW DELHI: Production of drugs and pharmaceuticals continued to show an upward trend in 1988-89, according to the Annual Report of the Department of Chemicals & Petrochemicals, Ministry of Industry, Government of India.

As against Rs. 377 crores of bulk drugs and Rs. 1,827 crores of formulations produced in 1984-85, production increased to Rs. 530 crores and Rs. 2,690 crore respectively in 1988-89. Significant increases in production were achieved during the year in antibiotics, chloramphenicol, ampicillin, doxycycline, sulphas, vitamins, INH, ethambutol, chloroquin phosphate, diloxanide furoate, propanolol and methyl dopa. In some cases there was a decline in production caused by cheaper production by the small sector. Hence the availability of these drugs has not been adversely affected, the report adds.

Export of drugs increased to Rs. 289.60 crores in 1987-88 against Rs. 222.96 crores in the previous year. A perspective plan for 15 years has been drawn up for export. The following table indicates the trend of production of bulk drugs and formulations:

Import of bulk drugs, intermediates, and chemical solvents increased to Rs. 343.50 crores (CIF) in 1987-88, against Rs. 285.96 crores in 1986-87. 40 letters of intent and 20 industrial licences were issued in 1987-88

(Rs. crores)

Year	*Bulk Drugs*	*Formulations*
1984-85	377	1,827
1985-86	416	1,945
1986-87	458	2,140
1987-88	480	2,350
1988-89	530	2,690
1989-90 (Estimate)	607	2,800

The trend of export is indicated in the following table:

Export of Drugs*

Year	*(Rs. crores)*
1984-85	217.00
1985-86	265.00
1986-87	222.96
1987-88	289.60
1988-89 (Estimate)	350.00
1989-90 (Estimate)	400.00

* Includes medicinal castor oil.

of these, 4 letters of intent and 3 industrial licences were issued to FERA companies. In addition, 192 DGTD registrations and 65 delicensing registrations were granted. 20 foreign collaborations were approved in 1988.

The report describes the various steps taken by the Government to promote the orderly, planned growth of the pharmaceutical industry. The three-pronged strategy adopted to implement the policy of liberalisation of industrial licensing procedure consisted of (1) delicensing of 94 drugs, (2) broad-banding of 31 groups of drugs on the basis of similarity of plant design, process and production facilities, and (3) fixation of minimum econimic capacities in respect of certain drug to enable the manufacturers to avail of economies of scale.

DRUG CONTROL NEWS

Drug Control Infrasturctrue

NEW DELHI: Mrs. Saroj Khaparde, Minister of Health said in Lok Sabha recently that Thirteen out of 29 States and Union Territories in the country have full time Drugs Controllers; sixteen States and Union Territories have only part-time Drugs Controllers.

The number of drug inspectors in the State and Union Territories was 664 as on April 1, 1988, as against 2,689 drug inspectors required as per the norms recommended by the Task Force on Spurious and Substandard Drugs. The norms were one drug inspector for 25 manufacturing premises and one drug inspector for 100 sales premises.

Beware Of Banned Drugs

CALCUTTA. The Drug Action Forum gave a call for total boycott of all products of five drug companies to discourage the use of banned drugs in the State, Dr. Sujit Das, secretary of the Forum in West Bengal, said at a Press conference recently that even though the Government of India had banned about a thousand drugs in 1983, the concerned drug companies had obtained stay orders from courts of law and continued to sell all kinds of spurious drugs.

The Forum members pointed out that a boycott movement had been organised to bring the State Go-

vernment's attention to take positive measures against these drug companies.

This was the first time in the State where a consumer resistance was being put up against five companies to compel them to withdraw all harmful drugs. A letter was also sent to the Union Health Minister and the Health Secretary. Members of the Indian Medical Association, Indian Association of paediatries and the Health Service Association have also participated in the boycott movement, Dr. Das said.

Sale Of 6 Drugs Banned

BOMBAY: Sale and distribution of six drugs, reported to be of sub standard quality by the government analyst, Drugs Control Laboratory, Maharashtra state, Bombay has been banned under the drugs and cosmetics Act 1940.

The sub-standard drugs are (name of the drug, batch no, name of the manufacturer) rubycot, Ruby Surgical and Allied Products Pvt. Ltd, Jalgaon, bisocardyl tabs, I.P. 5, Samarth Pharmaceuticals, Bombay; Atropine sulphate inj. I.P. for, Wison Pharma, Kolhapur Aspirin Tabs, I.P. AS7506, Medico Pharma, Bombay, Oxytetracycline Inj. I.P. 280, Antrix Pharmaceuticals Ankleshwar (Gujarat), and Aspirin tabs. I.P. 6925, Eupharma Laboratories, Bombay, according to an official release here.

The manufacturers of the drugs have been directed to stop sale, to recall the stock already sold to intimate details of stock and to stop manufacture of the drugs in question, the release added.

New Drugs Approved In 1988

NEW DELHI : The Drugs Controller, India has granted marketing permission for 23 new drugs under Rule 30-A of the Drugs and Cosmetics Rules, 1945, during the period January 1, 1988 to October 31, 1988. The new drugs approved, with their indication given in brackets, are: Etoposide (anti-cancer), Bezafibrate, Amineptine and Gemfibrozil (lipid-lowering agents) Astemazole (anti-depressant), Budesonide (anti-allergic), Penfluridol (anti-asthmatic), Aclarubicin (neuroleptic agent), Zidovidine (anti-cancer), Ceftriazone Sodium (anti-viral), Minoxidil (alopecia), Benzydamine (topical analgesic), Interferon Alfa 2-B (anti-cancer), Melagenina (extract of human placenta), Amrinone (inotropic agent), Ethamsylate (anti-hoemostatic), Minocycline Cefuroxime and Ceftazidime Pentahydrate (antibiotics-Alprozolam (anxiolytic agent), Tertatolol HCl (anti-hypertensive), Cyclosporin (immuno-suppressant), Triclabendazole (Vet) (broad spectrum anthelmintic).]

Panel To Review Drug Control

MADRAS: The Central Council of Health has suggested setting up a high-power group of State Health Ministers and Drug Controllers for restructuring the machinery with particular reference to the constitution of a National Drugs Control Authority (NDCA).

This and other recommendations of the Council, including those on guidelines for procurement. storage distribution and withdrawal of drugs in Government hospitals are viewed by quence, especially in the context of the existing short comings in the implementation of the Drugs and Cosmetics Act.

The Council's concern stems from the decision of the Union Government to take corrective steps to make drug control machinery more effective following the observations of the Lentin Commission which went into the deaths due to administration of glycerol in a Bombay hospital last year.

While the manufacture, sale and distribution are under the control of the State authorities, the Centre is responsible for the quality of imported drugs, registrations and approval of new formulations, laying down standards and amendment of the Drugs and Cosmetic Act and Rules.

The Council has identified and the following difficulties and deficiencies in the implementation of the Drugs Act: (i) Lack of adequate testing facilities in States—only four States have full fledged laboratories and 10 have facilities only the test non biological drugs. As a result, only 24,000 samples are tested every year as against the 16,000 manufacturing units; (ii) lack of adequate staff in the Drug Inspectorates of States and the centre. There are 664 inspectors in the country as against 2,689 recommended by the Task Force; (iii) lack of effective action against manufacturers of sub-standard/spurious drugs partly due to inadequate staff testing facilities taking punitive action; and (iv) lack of effective mechanism to recall drugs reported to be not of standard quality, especially in emergency situations.

The high-power group will include senior officers in the Union Health Ministry and review, among other things, the existing powers relating to recall of drugs in emergency situations, "Recommendations of this group should be finalised within two months," says the Council.

The idea of a National drug Control Authority was in fact recommended even in 1975 by the Hathi Committees on Drugs and Pharmaceutical industry appointed by the Government. It envisaged it as a statutory body with certain well defined functions including the continuous assessment of the national needs of essential drugs in the context of prevalent diseases. The NDCA should also plan programmes, coordinate and monitor the production of essential bulk drugs and formulations laying down relative priorities, locate raw materials and recommend price maxima in consultation with the Bureau of Industrial Costs and Prices. Questions were raised in Parliament as to why the Government had not constituted the NDCA as recommended by the Hathi Committee.

Significant among the recommendations of the Central Council is that each State should have a whole time Drugs Controller for effective implementation of the Drugs and Cosmetics Act and other related legisla-

tion. Enquiries show that the amended through a notification issued in the Gazette of India Extraordinary dated April 12 wherein qualifications for licensing and control authorities have been prescribed.

The Council has called for rigid and regular inspection by the State Drug Control organisation of firms prior to grant/renewal of licences. "Requirement of testing laboratories should be insisted upon. No licelicence should be granted to any unit which does not have in-house testing facilities for new materials and finished formulations. For effective check on movement of spurious drugs, every State should set up an intelligence-cum-legal cell with facilities for quick mobility and communications. besides taking prompt action against reports of sub-standard drugs, the Drug Controllers should enforce the provisions of Schedule amended to incorporate good manufacturing practice.

For improving the quality of drugs that are routed through Government medical institutions which largely cater to the needs of the poor, the Council has stated that the State Drug Controllers should issue guidelines for procurement, storage distribution and withdrawal of Drugs in the Government hospitals. And "to ensure supply drugs of highest quality to these institutions, State Drug Controllers should invariably be associated to identify manufacturers from whom purchases can be made. This list of manufacturers would be shortlisted and their name circulated to all indenting Government agencies.

In the absence of such guidelines each State is following its own policy. Some units order their requirements from the public sector and joint sector undertakings. Instances are not wanting where the drugs indented are different from the drugs received. Knowledgeable sources say that such practices escape detection by the enforcement agencies as the purchase records are available with the accounts office while the drugs are kept in the hospital stores, thus leaving scope for pilferage and misuse.

Recently, the Central Drugs Centre organisation in Madras detected a case where against the orders for supply of a drug (Lysol) manufactured by a public sector undertakings, a local firm applied it bearing the name of the public sector undertaking. There are also instances where some of the institutions have purchased through super markets transfusions rejected by the Central purchase committee. Drugs purchases, according to sources, are deliberately routed through super markets to favour select firms at high prices and also for evading sales tax.

4 Substandard Drugs Banned

BOMBAY: The government analyst, drugs control laboratory, Maharashtra state, Bombay, has reported four drugs to be not of standard quality. The sale and distribution of these drugs are banned under the Drugs and Cosmetics Act, 1940.

Name of these drugs: batch no. and name of manufacturer are: AcmeFem Tablets S-223, Acme Pharmaceuticals, Thane; Aspirin Tablets I.P. As-7550, Medico Pharma, Bombay; Arocin Fort Tablets 2840, Royal Laboratories, Indore (MP) and Metotid Tablets G-85592, Biological Evans Ltd., Patancheru.

Steps have been taken to stop manufacturing, and recalling the stock of these drugs already sold in the state. Also, the drugs controller of the other states have been intimated in this regard for similar action, an official said.

Drugs Control In Karnataka

BANGALORE: A Press release by the Drug control Department about the Drugs Control activity in the State for April, 1989 says that 9 Complaints under the Drugs & Cosmetics Act, 1940 and Rules thereunder were received during the month, 28 complaints under the Drugs and Cosmetics Act, 1940 and Rules thereunder and Drugs (Price Control) Order, 1979 were investigated. Necessary action has been initiated in these cases.

One prosecution case under the Drugs and Cosmetics Act, 1940 and Rules thereunder was decided and acquitted.

Show Cause Notices were issued to 14 manufacturing firms and 17 sales establishments for various contraventions committed by them under the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Two licences of manufacturing units and 29 licences of sales establishments were cancelled due to change in the constitution/premises. 9 licences of sales establishments were suspended for various contraventions committed by them under Drugs and Cosmetics Act, 1940 and Rules thereunder. 11 sale Licensses were warned for having contravened the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder during the month under report.

10 Licences of manufacturing units and 216 licences of sales establishments were granted. 24 Licences of manufacturing units and 225 licences of sales establishments were renewed during the month under report.

916 sales premises, 27 manufacturing units and 7 Hospitals were inspected by the Inspectorate staff of this Department during the month under report.

57 samples of Drugs were drawn by the Drugs Inspectors or Test and Analysis during the month.

New Drugs Controller Of Rajasthan

JAIPUR: Dr. A.O. Khan has been appointed as new Drugs Controller of Rajasthan. Dr. Khan has taken the charge of Drugs Controller and licensing Authority from June 1, 1989.

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- INVERTASE
- LACTASE
- LIPASE
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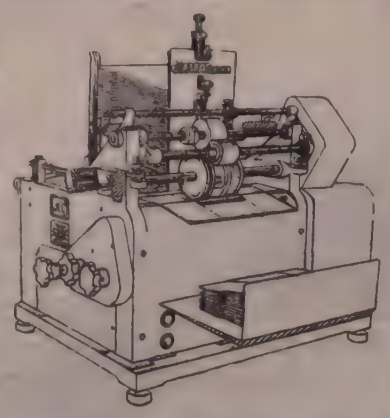

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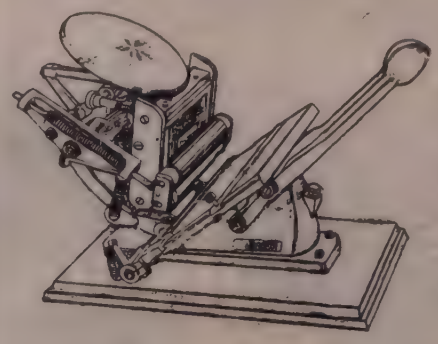

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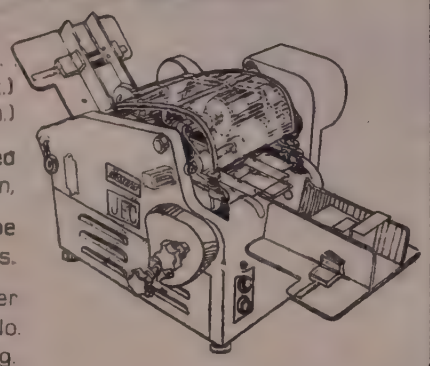

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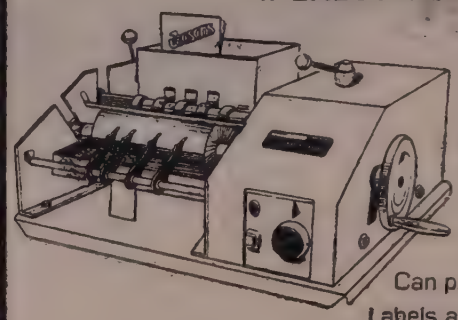

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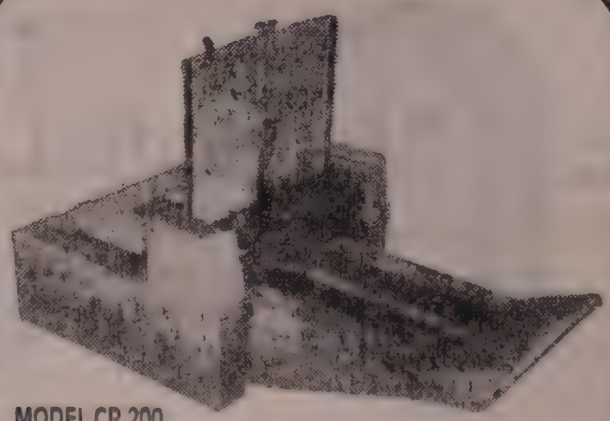

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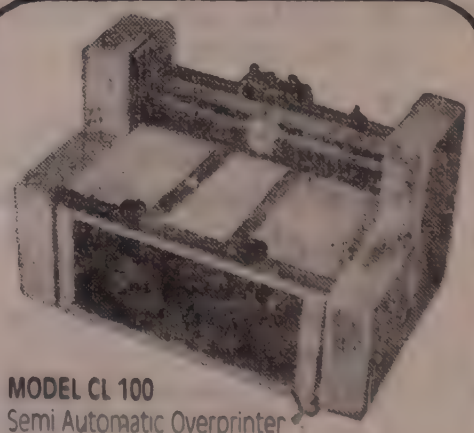

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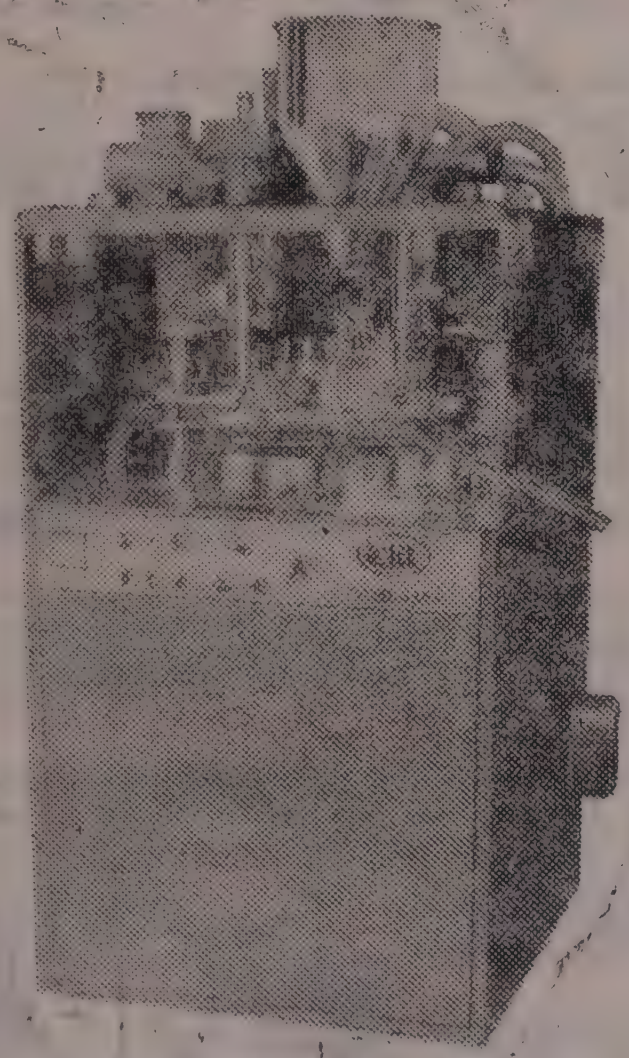

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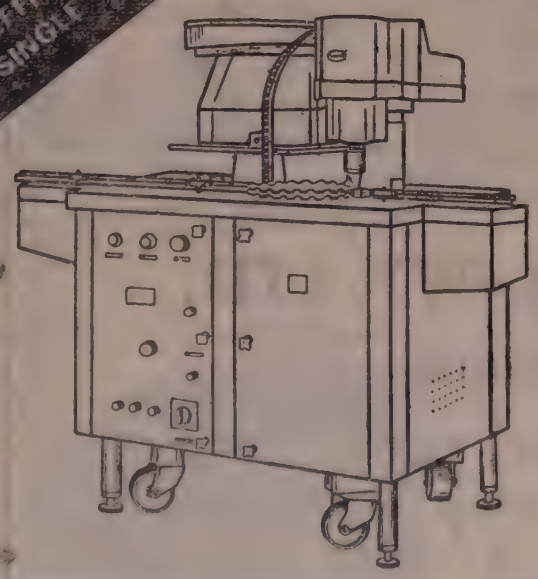

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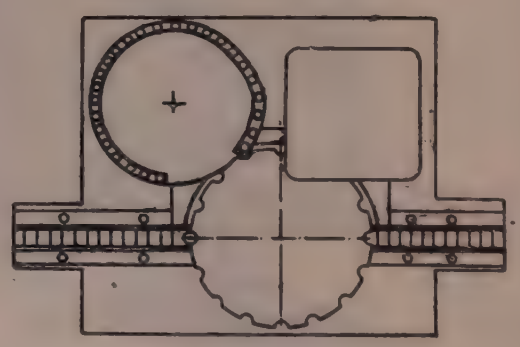

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NEWS OF THE INDUSTRY

East India Pharma To Diversify

CALCUTTA : The East India Pharmaceutical Works Limited (EIPWL) will shortly enter the state-of-the-art biotechnology area in collaboration with Indotech Inc. a non-resident Indian firm in the US.

Indotech Inc, led by Dr Ananda Mohan Chakraborty, a renowned expert EIPWL will set up a joint venture—Indobiogen Pvt. Ltd—in biotechnology and which will have its frontline technological unit in south 24 Parganas near Calcutta. Though the unit will initially concentrate on biochemical items, it will also manufacture water purifiers and diagnostic kits, which are rarely available in the country.

Mr. Amit Sen, managing director of EIPWL, told the press that while the US firm will have two-third stake in the joint venture company, EIPWL will hold the balance of the Rs. 1.5 crore equity.

Mr Sen said that the total investment on the project will involve Rs 4.5 crore and the promoters of Indobiogen Pvt Ltd will approach the financial institutions for financing the balance of the project cost. It is estimated that around Rs. 50 lakh worth of foreign exchange will be required for importing some vital equipment.

Mr. Sachi N. Neogy, managing director of indobiogen, said that the project will bring in the latest hyberdorma technology, which will encompass the whole range of diagnostic, preventive as well as curative apparatus and medicines.

In the initial stage, the new company will import biochemical reagents from Indotech to be packed and supplied to about 180 research institutions in the country. This will be the pre-production familiarisation programme of the new company, which is expected to begin production within one year of setting up of the unit.

Mr. Neogy said that the new company will have a low workforce.mostly scientists and technocrats. He also said that the company's products will have to be kept at temperatures between 7 degree and 4 degree celsisus, for which special packaging system will have to be developed.

EIPWL amended its memorandum of association in 1987 to diversify its area of production. The company also made changes in the articles of association, which empowered its board of directors to allow appointment of direcrors from the financial institutions.

Sumitra Pharma To Go On Stream Soon

HYDERABAD : The Rs. 615 lakhs bulk drugs project of Sumitra Pharmacuticals and Chemicals Ltd. (SPLC) coming up fast at Gidwal village in Medak district, 90 km from here on Bombay Highway will go on stream by October/November this year according to Mr. Ramesh Jain, Managing Director of the company.

The company is setting up a Rs. 6.15-crore project to manufacture 2,000 tonnes of ibuprofen and 50 tonnes of mebendazole per annum. The project cost will be met through the equity capital of Rs. 4.15 crores out of which Rs. 1.07 crores will be contributed by promoters and Rs. 3.08 crores will be offered to the public.The balance of Rs. 2 crores will be financed through term loans.

The company hopes to enter the capital market sometime in August next to raise Rs. 3.08 crores, out of which Rs. 1.23 cores will be reserved for NRIs, Rs. 20 lakhs for SBI capital market and five per cent of the issue to the employees. The issue has been fully tied-up for uderwriting. The company has been permitted to retain over subscription upto 15 per cent of the issue.

Addressing newsmen here, Mr. Jain said that SPCL was among the first few in the country to have adopted the "swing plant" concept that enabled the unit to increase the capacity of ibuprofen from 300 tonnes per annum to 400 tonnes by utilising the capacity of 50 tonnes per annum for mebendazole and vice versa. The company has licence to manufacture 2,000 tonnes of ibuprofen and 500 tonnes of mebendazole per annum.

Mr. Jain said that the enqiry for the project amounted to Rs. 415 lakhs and the terms loans Rs. 100 lakhs each from SBI Capital Markets and State Bank of Hyderabad. This gave the company a strong equity base and in future it could go in for expansion of capacity and technology upgradation by seeking term loans, if needed.

Referring to global demand for ibuprofen, the Managing Director said India's current market share was only 400 tonnes which left an additional import potential of atleast 800 tonne per annum envisaging a 15 per cent of the global market share. Developed countries are not stepping up their capacities anymore. Domestic demand, similarly, has an existing supply gap of 500 tonnes per annum according to Mr. Jain, Mebenzadole has also export demand as well as local demand.

Since exports fetched a far higher price than domestic market, SPCL had drawn up plans to export 70 per cent of its output. Process for approval and clearance by the US Food and Drugs Administration for the company's products has already been initiated and SPCL could be-

come the second unit in the country to gain this approval for ibuprofen, Mr. Jain said.

SPCL will be going to the capital market sometime in August this year to raise Rs. 308 lakhs of which Rs. Rs. 123.20 lakhs will be reserved for NRIs, Rs. 20 lakhs for SBI Capital Markets and five per cent of the issue to employees. The issue has been fully tied-up for underwriting.

The company's board is headed by Mr. V. N. Nadkarni as Chairman (former Chairman of SBI), and has on its board among others, Mr, N.N. Pai, former Chairman IDBI, Mr. M.V. Subba Rao, former Chairman and M.D. Indian Bank, Dr. K. Lahiri, MD TTK chemicals, Dr. Vishnu Padwal, formerly of Boeringer Knoll Ltd. and Mr. B. D. Jain.

Searle Plans Rs. 5-cr. Outlay

BOMBAY : Searle India Ltd. has planned for a capital outlay of Rs. 5 crores over the next two years.

While the company will be basically strengthening its presence in agrochemicals and pharmaceuticals through expansion and modernisation schemes, it is simultaneously exploring possibilities for entering the field of consumer items.

The company's financial performance during the 15-month period ended March, 1989 has been indifferent. While sales have registered an increase from Rs. 35.00 crores during the year ended December, 1987, to Rs. Rs. 52 crores, gross profits have risen marginally to Rs. 6.54 crores, from Rs. 6.22 crores. On an annualised basis, however, gross profits have declined as have profits afrer tax. In fact. Searle India's performance started declining in 1987, when sales dropped to Rs. 35 crores, from Rs. 41.10 crores in the previous year and profits before tax slipped to Rs. 3.74 crores, from Rs. 5.00 crores. Under the circumstances, the management has slashed the dividend to six per cent on the enhanced capital of Rs. 5.2 crores for the 15 months ended March, 1898, from 20 per cent in 1987 and 1986.

According to Dr. R. N. Goel, president and managing director, the main reason for the company's lacklustre performance has been the fall in the sales of agrochemicals on account of the drought in 1987. While the monsoon was good in 1988, stiff competition has resulted in a squeeze on margins, Dr Goel points out. A shortage of raw materials in 1988, when the demand was picking up, also hit production and sales, the managing director observes.

More than 50 per cent of Searle's turnover comes from the sales of agrochemicals. This division is also the major profit-earner. Consequently, the overall performance of the company has suffered in the past two years, However, the managing director is hopeful that 1989-90 would see a turnaround in the fortunes of the company and that sales would pick up by about 15 per cent.

Searle proposes to modernise its unit at Thane at a cost of Rs. 2 crores and the work is expected to be completed by 1991. The scheme envisages installation of an incinerator for effluent disposal.

It is also taking up the backward integration programme for its butachlor unit at Ankleshwar which was commissioned last year. A new plant will be set up entailing an investment of around Rs. 3 crores. The plant is scheduled to go on stream in mid-1990, according to Dr Goel. Both these schemes are to be financed from internal accruals.

As for pharmaceuticals, the managing director notes that, as a result of the price control policy, profit margins are low. The company is nevertheless planning to take up manufacture of basic drugs and formulations and is looking for technical collaborations.

Searle also proposes to launch a sugar-free sweetner —Equal—early next year. The bulk material would be imported from Nutra Sweet and made into pellets here, the managing director explained. The company is also toying with the idea of launching a chocolate drink.

Hindustan Ciba-Geigy Does Well

BOMBAY : Hindustan Ciba-Geigy has done well in terms of business growth during the 15-month period ended March 1989. The directors have recommended a dividend at 30 per cent which will absorb Rs. 5.31 crores against Rs. 3.54 crores last year (20 per cent). The company has reported a growth of 44 per cent in sales over 1987 and an overall improvement in its working results for the period. On an annulaised basis, the growth in sales is 16 per cent.

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Sales have risen from Rs. 176.79 crores in 1987 to Rs. 255.49 crores. The gross profits is up by 76 per cent. from Rs. 17.83 crores to Rs. 31.40 crores. Annualised increase is 41 per cent. After providing for depreciation (Rs. 7.26 crores against Rs. 6.14 crores) and taxes (Rs. 10.55 crores against Rs' 4.93 crores), the surplus profit available is Rs. 13.59 crores against Rs. 6.76 crores, which is twice that of 1987.

TN Dadha Pharmaceuticals Pays 12%

MADRAS : The joint sector Tamil Nadu Dadha Pharmaceuticals is paying 12 per cent, inclusive of dividend on bonus shares for two months, for the nine months to March against 16 per cent for the previous 12 months.

Turnover and gross profits, before depreciation and taxation, were only marginally higher on an annalised basis for the nine-month period at Rs. 18.17 crore (Rs. 23.17 crore) and Rs. 96.27 lakh (Rs. 1.25 crore). On an annualised basis depreciation provision was higher (Rs. 35.48 lakh against Rs. 44.18 lakh) while tax provision was just around 40 per cent (Rs. 7.61 lakh against Rs. 24.9 lakh).

The previous 12 months' disposable funds swelled by a write back of Rs. 1.25 crore of depreciation. Brought-forward surplus was only Rs. 4.49 lakh. In the nine-month period, brought-forward surplus was Rs. 26.29 lakh. General reserve got only Rs. 6 lakh againsts Rs. 14 crore in the previous period. The surplus carried forward is Rs. 57.97 lakh against Rs. 14.73 lakh consumed by the proposed dividend (Rs. 17.65 lakh).

The directors have reported that a case in the Supreme Court against the price fixation order of the government issued in 1981 has failed. Following this it has to deposit the difference between the selling price of the bulk drug, calcium lactate, and the price under the notification. The company, as directed by the Supreme Court, has filed price review positions.

The cost of production during the period has been substantially higher than sales realisation, as has been certified by the statutory cost auditor, It resulted in a sales slump of the drug during the period. The company will not be liable as a consequence of the Supreme Court judgment, they have said.

The directors have also said that from August, 1987, the product has been outside price control, but the company filed an application for a maximum selling price of Rs. 29.75 per kg and has voluntarily reduced this to Rs. 28.75.

Atul Products Proposes 28%

BOMBAY : The directors of Atul Products have proposed a dividend of 28 per cent for the 15 months period ended March 1989 after appropriate rounding off in order to achieve an annualised rate of 22 per cent. It may be noted that the amalgamation of Atul Products Ltd. with Gujarat Aromatics Ltd. was effected during the year and the name of amalgamated company, namely Gujarat Aromatics was changed to Atul Products Ltd. simultaneously. The erstwhile Atul had declared a dividend of 20 per cent for the previous year ended December 1987.

The company has given the previous year's figures showing the combined results of both Atul and Aromatics unit for the purpose of comparison.

Sales turnover during the period amounted Rs. 182.89 crores against Rs. 98.43 crores and gross profit amounted to Rs. 980 lakhs against Rs. 466 lakhs. After depreciation (Rs. 430 lakhs against Rs. 14 lakhs) and taxation (Rs. 45 lakhs against nil), the profit after taxation amounted to Rs. 385 lakhs against Rs. 14 lakhs.

It may be noted that profit for the year is achieved after absorbing net loss of Rs. 301 lakhs of the aromatics unit. The Aromatics unit is expected to achieve cash break even position during the current year.

The reserves and surplus of the company as on March 1989 amounted to Rs. 32.91 crores after giving the effect of the amalgamation and carried forward losses.

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Wage Freeze Plan In Calcutta Chem.

CALCUTTA : Shaw Wallace is planning to freeze the wages of the 1,300-strong workforce of its subsidiary, Calcutta Chemicals Ltd, for 24 months. The SWC management is also preparing a voluntary retirement scheme for a sizable number, which according to it has become surplus.

The wage-freeze, however will be implemented after a detailed discussion with the two labour unions of Calcutta Chemical. A high powered committee comprising five-senior managers of SWC and an equal number of trade union representatives has been formed to discuss the issue as also the workers' demands.

Besides the wage-freeze, the SWC management has also decided to stop free canteen facilities to the staff and workers of Calcutta chemical and withdraw free gifts of the company's products given to them every month. So far, all workers used to get three cakes of 'Margo' soap and a tube of the 'Neem toothpaste produced by the company free of charge every month. Mr. Kishore Chhabria has reportedly told the company employees that these facilities will be withdrawn, at least temporarily, to tide over the difficult financial situation that SWC is facing at present.

The SWC management has also issued transfer orders to six officers of Calcutta Chemical to take up new assignments at the company's production facilities at Kanpur. A number of workers will be asked to follow suit, according to sources.

Sources said this move indicated that the management was going back on a commitment it made to the West Bengal government that it would not resort to any redeployment, retrenchment or relocation of the employees of Calcutta Chemical. The company made this commitment when it sought the state industries directorate's permission to shift entire production facility from its premises at 35 Panditia Road, Calcutta to 67, Tiljala Road also in Calcutta.

The production at the two Calcutta Chemicals' factories in Madras and Calcutta has slumped to about 10 per cent of the capacity. At present, only the Margo soap and the Neem toothpaste are being produced. The range of pharmaceutical products, however, has been virtually shelved. The company has also surrendered some licences it held originally. The employees have been given to understand that the company has relinquished the existing licences as a pre-requisite to the change in location of the factory from Panditia Road to Tiljala in Calcutta. The state industries directorate has, however, maintained that no such surrender of production licences is required if the plant is being re-located within the same state.

Th SWC management has in the meantime applied for fresh licences. According to sources, it has received licences for the manufacture of liquid Winominus and Ferrowinominus tonic, products which were already within Calcutta Chemicals range of pharmaceutical products. SWC has also closed down the pharmaceutical operations in 16 of the 19 outlets within the country. Pharmaceutical products are being sold from three branches only namely, Calcutta, Patna and Ranchi.

While SWC has clipped the pharmaceutical division of Calcutta Chemical, it has continued to maintain that there are major plans to develop the pharmaceutical wing of the company Mr. George Daniel, erstwhile director of Hoechst India, has been brought in to head the pharmaceutical operations. Another person was recruited to help Mr. Daniel, but he has since left. Sources said the SWC management had earlier promised to pump in about Rs. 5 crore to revive the dwindling operations of the company, though nothing has been done yet. The trade unions have suggested that the company resume production of stearic acid, water, oleic acid, calcium lactate powder, spiritious medicinal items and ethyl oleate, which had been very profitable items in the past. They have also suggested that excessive reliance on the production of Margo soap was not a prudent decision and the management should contemplate adding other varieties of cheaper soaps to the range to improve margins.

Meanwhile, the Shaw Wallace management has not stopped any salary or wage payment to the employees, but has delayed increments that are due as per the wage settlement which expires in 1990.

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Roche Products Good Working

BOMBAY : Roche Products, which turned out good working results for 1988, is doing well in the current year too. Its turnover during the first 5 months of 1989 has been 16 per cent higher than that of the corresponding period of 1988.

According to Mr. R.A. Shah, chairman, in the interest of overall safety of the plant and personnel it has become imperative for the company this year to effect substantial investments in, what may be considered to be unproductive assets, such as, uderground storage tanks. The present tanks are rather antiquated and it is essential to replace them.

Jayanti Vitamins

HYDERABAD : The directors of Jayanti Vitamins Ltd. propose to issue 4.07 lakhs—14 per cent secured partly convertible debentures of Rs. 100 each aggregating Rs. 4.07 crores on rights basis in the ratio of one debenture for 10 shares held, including five per cent to employees and working directors.

Each debenture of Rs. 100 each will consists of three parts. Part A of convertible portion of Rs. 10 paid up share to be issued at a premium of Rs. 10 per share in March 1990. Part B also of convertible portion of Rs. 10-paid up share to be issued at a premium of Rs. 20 per share in March 1991 and Part C will be non-covertible portion of Rs. 50 per debenture to be redeemed at the end of 7, 8 and 9 year.

The company also proposes to issue two lakhs—14 per cent secured partly convertible placement of Rs. 100 each agreegating Rs. two crores on private placement basis to the financial institutions, mutual fund and merchant bankers. The company will also make a issue of three lakhs 14 per cent non-convertible debentures aggregating Rs. 3 crores on private placement basis.

ICI Begins Output Of New Drug

MADRAS : ICI India, which began production of one of its globally accepted therapy for hypertension in a new Rs. 5 crore facility here will market the drug at just one-eighth of the price it is sold in the UK.

Tenormin, which has been in the global market for about 10 years now, will cost Indian consumer just under Rs. 2 against Rs. 15-18 paid by their British counterparts.

ICI's international marketing director, Dr. T. Medinger, visiting ICI-India's only Pharmaceutical factory in India located north of Madras city, told newsmen that though it has cost a fortune to develop the medicine, ICI is not charging the Indian customer the R and D costs. However, he admitted, if we were to charge the Indian price globally, we will just not survive."

Dr. Medinger denied charges that ICI, has already squeezed enough out of the markets and is now trying to appease the customer.

ICI, which has the 10th largest research and development outfit in the world, spends 15 per cent of the revenues from its pharmaceutical division on research. The company will spend around Rs. 7500 crore on research and development in the next decade, Dr. Medinger said, adding that all this has to go into the price of the medicines."

Reiterating the importance of proper research and development, Dr. Medinger said such a huge expenditure is necessary for surviving in a highly competitive market.

New Drug For Hypertension

MADRAS : A new first line anti-hypertensive therapy drug was introduced in the country by the ICI (India) Limited recently.

Formally inaugurating the sales of the drug here, 'Tenormin,' Dr. T Medinger, said the ICI had a number of 'notable firsts' in the field of pharmaceuticals, including, the first prophylactic anti-malaria drug.

Astra-IDL Improves Its Performance

BANGALORE: Bangalore-based Astra IDL Limited improved has its performance for the nine-months ended March 31, 1989. Sales have been Rs. 1398 lakhs as against Rs. 1612 lakhs for the full year ended June 30, Sales have gone up by 16 per cent compared with the corresponding period of previous year.

Profit before tax is higher at Rs. 116 lakhs (Rs. 91 lakhs). Net profit available for appropriation is Rs. 92 lakhs (Rs. 56 lakhs) after providing for taxation Rs. 24 lakhs (Rs. 24 lakhs).

The board of directors have recommended dividend at 10 per cent for the nine-month period, absorbing Rs. 25 lakhs. This dividend works out to 13 per cent on annualised basis.

The company successfully launched sensor caine, a long acting local anaesthetic and theobric, a combination broncho dialator for asthma. Plans are afoot to launch products, based on original research of Astra in the fields of gastroenterology, hypertension and asthma.

Spencer & Co. Ltd. Declares 25% Dividend

MADRAS: The board of directors of Spencer & Co. Ltd. has declared a final dividend of 25 per cent in addition to the interim dividend of 15 per cent, thereby making a total of 40 per cent against 20 per cent in the previous year.

The company has reported a pre-depreciation profit of Rs. 108.77 lakhs for the 18-month period ended

December 31, 1988, as compared to Rs. 56.40 lakhs in the previous year consisting of 12 months.

However, in view of the company's expanded equipment leasing activities, the provision for depreciation has been higher at Rs. 65.36 lakhs against Rs. 13.99 lakhs in the previous year. Profit after providing for depreciation and taxation stood at Rs. 37.23 lakhs (Rs. 40.05 lakhs).

Eskayef To Pay 27 Per Cent

BOMBAY : The directors of Eskayef have decided to pay a final dividend of 15 per cent for the 16-month period ended March 31, 1989. This makes a total distribution of 27 per cent on the capital increased by a one-for-two bonus issue, as againast 25 per cent paid for the previous year of 12 months on the old capital.

The company has fared well with its turnover rising from Rs. 64 crore in the previous year to Rs. 93.88 crore and gross profit from Rs. 10.20 crore to Rs, 13.62 crore, according to preliminary figures.

With depreciation claiming Rs. 46.80 lakh against Rs. 72.47 lakh and tax liability Rs. 4.55 lakh crore against Rs. 3.76 crore, there is a net profit of Rs. 860 crore compared to Rs. 5.79 crore in 1987. Out of this, total dividend distribution will absorb Rs. 202.50 lakh (Rs. 125 lakh). General reserve gets Rs. 6.58 crore (Rs. 4.53 crore).

Empire Medicines Rights Issue

BOMBAY : Empire Medicines is coming out with a rights issue totalling Rs. one crore. The issue is being made to finance the long term margins money for working capital as also its proposed extension/diversification into bulk drugs.

The company has in the past two years consistently paid a 20 per cent dividend. During the year ended March 1989, it earned a gross income of Rs. 100 lakhs in leasing and Rs. 40 lakhs in pharmaceutical sales. The provisional figures during the year shows that the company would be in a position to maintain the same pay out ratio. During the curent year, the turnover of pharmaceutical sales is expected to jump to Rs. 250 lakhs.

The company is actively considering setting up a factory to manufacture bulk drugs.

Punjab Chem. & Pharma Net Prcfit 2.5 Crores

CHANDIGARH : Punjab Chemicals and Pharmaceuticals Limited has announced a turnover of Rs. 15.26 crore for the 18-month period ended March 31, 1989, as compared to Rs. 4.86 crore in the previous 12-month period.

Gross profit for the period was Rs. 3.74 crore (Rs. 60.45 lakh in the previous 12 months) and after providing a depreciation of Rs. 73.14 lakh the profit amounted to Rs. 3.01 crore. After various appropriations, including the loss for the previous year, being wiped out the net profit was Rs. 2.53 crore.

The board of directors has recommended a final dividend of 35 per cent above the two interim dividends of 20 per cent each. This makes the total divided for the period ended March 31, 1989 around 75 per cent in 18 months.

The company has announced a book closure from September 1 to September 15. The annual general meeting will be held on September 16 at Chandigarh.

The company's earning per share has gone up a phenomenal Rs. 30.75 as comapred to Rs. 2.65 previously (year ended September 1987).

Sandoz (India) Fares Well

BOMBAY : Sandoz (India) has been faring well during the current year with increase in turnover by 22 per cent during the first five months (January to May 1989) at Rs. 52 crores as compared to the same period last year.

Revealing this at the annual general meeting of the company, the managing director, Mr. J. P. Hayoz, said that the growth in domestic sales have been slower at 14 per cent but that of exports have doubled. The sales of agro division has been adversely affected in view of slower growth of farm products due to weak monsoon, but the chemicals and pharma divisions both progressed with double digit figures.

On export front, the company has orders on hand woth Rs. 28 crores against Rs. 17 crores last year. While Rs. 10 crores worth of orders have already been executed, the balance will be executed in the coming months.

Citurgia Repeats The Dividend

BOMBAY : Despite a setback, Citurgia Biochemicals has repeated the dividend at 35 per cent for the year ended March 1989.

Although the total turnover is up to Rs. 28.33 crores from Rs. 25.02 crores, the gross profit has dropped to Rs. 5.60 crores from Rs. 6.12 crores last year. The net profit is Rs. 256.36 lakhs against Rs. 292.80 lakhs after depreciation (Rs. 128.34 lakhs against Rs. 173.89 lakhs), investment allowance reserve (Rs. 25.12 lakhs against nil) and taxation (Rs. 150 lakhs against Rs. 145 lakhs).

After adjustments, the disposable profit is Rs. 322.21 lakhs against Rs. 341.89 lakhs. The proposed dividend will absorb Rs. 118.34 lakhs as last year.

BASF India Shows Improved Results

BOMBAY : BASF India has shown improved results during the 15-month period ended March 1989. The

directors have recommended a dividend of 25 per cent. The bonus shares allotted on August 25, 1988, are entitled to pro-rata dividend for part of the financial year commencing from September 1988. The rate of dividend for the year ended December 1987 was 20 per cent. The dividend will absorb Rs. 89.64 lakhs against Rs. 58.46 lakhs.

During the period, income amounted to Rs. 89.89 crores against Rs. 59.26 crores in the previous year. The company has earned a gross profit of Rs. 13.91 croes against Rs. 9.20 crores. After depreciation (Rs. 275.84 lakhs against Rs. 199.77 lakhs), interest (Rs. 358.94 lakhs against Rs. 294.74 lakhs), and taxation (Rs. 390 lakhs against Rs. 220 lakhs), and certain adjustments, the surplus before other provisions amounted to Rs. 351.37 lakhs against Rs. 237.96 lakhs.

The appropriations are: investment allowance reserve (Rs. 26 lakhs against Rs. 1.30 lakhs), export profit reserve (nil against Rs. 4 lakhs), proposed dividend (Rs. 89.64 lakhs against Rs. 58.46 lakhs) and general reserve (Rs. 235.73 lakhs against Rs. 29.99 lakhs).

Pharmaceutical Products Of India

BOMBAY : Pharmaceutical Products of India went public on May 31, 1989 with an issue of 6.50 lakh equity shares of Rs. 10 each. Out of the present issue. UTI has undertaken to subscribe on firm allotment basis for one lakh shares.

The company has been promoted by Mr. M. K. Rayana and associates. Mr. Rayana is a qualified pharmacist and a technocrat. The equity for the promoters is Rs. 35 lakhs. After the public issue the company will cease to be a FERA company. The present non-resident Indians equity is above 40 per cent. The company profit-making is engaged in the manufacture of formulations.

The company is setting up a new bulk drug and formulation project at Tarapur, near Bombay. The bulk drug unit will be equipped with multi-purpose plant and machinery. This unit will initially manufacture Trimethoprim. The formulation unit will be equipped with sophisticated injectable, tablet, liquid oral, ointment and capsule departments. The cost of the project is Rs. 156 lakhs.

The basic engineering for the bulk drug plant is complete. The formulation unit is at an advanced stage of implementation. The bulk drug project is expected to be commissioned by November and the formulation project thereafter.

The demand for drug and pharmaceutical products is rapidly growing in the country. The company expects good demand for Trimethoprim and other products. It expects a turnover of Rs. 2.50 crores for the year ending March 1990. It is also hopeful of paying a dividend for 1989-90.

ICI (India) Planning Expansions

MADRAS : ICI (India) Ltd is planning a grand expansions in drug industrya rd hopes to introduce new drugs discovered by its parent company in the Indian market in the coming years. Almost 90% of the products marketed by ICI Pharmls. worldwide are a result of the companys own research. In terms of R & D manpower (3,000 employees) ICI ranks 10th in the world league. About 15% of the pharmaceuticals sales turnover is spent on research. Every day, ICI spends about Rs. 2 crores on pharmaceutical research.

ICI International plans to spend about Rs. 7,500 crores over the next ten years on medical research, according to Dr. T. Medinger, International Marketing Director. Current ICI rsearch focusses on cancer and cardio-vascular, pulmonary and arthritic diseases. Of the 20 largest selling drugs in the world, three are ICI brands. Dr. Medinger launched production of one of these, Tenrnormin (generic name atenolol) at ICI India's pharmaceutical and agrochemicals complex at Ennore, recently. Some Indian units are already making the drug from imported intermediates. ICI India is committed to producing the drug from its basic stage within 18 months. Tenormin is the world's third largest selling drug. It would be marketed in calendar packs for a fortnight's dose. The Rs. 5-crore plant has begun production.

By 1995, ICI India plans to launch new generation drugs, provided the market warrants setting up of viable capacities. New ICI drugs include Zoladex (goserelin), a once-a-month injection for prostratic cancer, Corwin (xamoterol) for heart failure and visacor (epanolol) for angina which is still under development. Mr. Inder Tandon, Chief Executive, Pharmaceuticals and Agrochemicals, said the company exported pharmaceutical and veterinary formulations worth Rs. 70 lakhs last year. Exports are being stepped up to Rs. 3 crores in the current year.

Dabur India Progress

NEW DELHI: Dabur India Limited had devoted over a hundred years to the care of mankind through quality Health Care Products like Chyawanaprash, Hajmola, Janamghutti, Sarbyna, Pudin Hara etc. and Family products like Amla Hair Oil, Red Tooth Powder, Sharbat-E-Azam to emerge as the single largest manufacturer of quality herbal products. The company's turnover has grown from a paltry Rs.1 crore in 1961-62 to Rs 105 crore in 1987-88, All this has been possible through consistent efforts by Dabur employees towards excellence in their work and the cooperative Dabur stockists—the testimony of all this being customer faith in their products. Moreover, decisive, clear and adaptive cooperative policy of the company venturing into new growth areas by way of diversiffication have also greatly contributed to their success.

The growth of Dabur has been phenomenal since the taking over of marketing and sales operations by Mr. S. Ramachandran, General Manager-Marketing in March 1983. Under his dynamic leadership, the turnover of the company has gone up from Rs 27 crores in

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1982 to Rs 105 crores in 1987-88, Mr. Ramachandran's outstanding professional capabilities have been recognized time and again by the professional bodies—in 1986, he was awarded the IMM—Tata Steel Marketing Man of the year Award.

In the past year Dabur has won several awards in appreciation of their work and more recently their chairman Mr. R.C. Burman has been awarded the "Man of the Decade Award for 1978-88 given by the International Business Council of India which is an organisation of leading entrepreneurs, businessmen, exporters and industry of India. The award is presented in recognition of excellent achievements in both public and private sectors. The board has opined that under his chairmanship Dabur products and medicines particularly Ayurvedic medicines and cosmetics have proved the hall mark of quality and dependability. Dabur also has recently been awarded the First Price of the Council For Fair Business Practices (CFBP) Jamnalal Bajaj Award in the manufacturing category. The CFBP awards were instituted to encourage high standards of integrity and fairness at every level of business practices in the interest of consumers and public at large". The CFBP award comes as a reaffirmation and acknowledgement of Dabur's time tested motto "What is that life worth which cannot bring comfort to others".

Dabur like the founder is first a company of compassion and philanthropy and only second a company of Business.

New Small Drug Unit Coming Up

CALCUTTA: Rose Modison (P) Ltd, will be the newest drug manufacturing unit to come up in south 24-Pargans under the SSI sector with a project investment of Rs 1 crore.

According to Mr Anupam Dasgupta, managing director, the company may go in for commercial production in the middle of next year and a plot of about five bighas of land has already been acquired for the new plant.

Reckitt & Colman Drug Division To Be Expanded

CALCUTTA: Reckitt and Colman India Limited (R and C), manufacturers of "dettol", "cherry blossom" and a host of other house-hold products, is now strengthening its pharmaceuticals division. Simiultaneously, the company is also gearing up to expand its range of house-hold products.

According to Mr R.S. Sikand, Managing Director, a new plant for the manufacture of pharmaceutical formulations has recently been commissioned in Mysore. An investment of Rs 2 crores has been made for the first phase of the project, which envisages manufacture of primarily analgesics in the tablet form.

In the second phase, which would require an investment of Rs 15 crores, formulations are to be produced in liquid form. This phase is scheduled to go on stream some time in 1990. Mr Sikand points out that R and C manufacturers basically anti-ulcer, anti-epilepsy and analgesic drugs, which as of now, contribute roughly 30 per cent to the turnover. With the pharmaceutical industry booming ,the new project should ensure good returns, Mr Sikand feels.

As regards house-hold products, R and C has definite plans to launch the "Binaca" range of toiletries in the not too distant future. Initially, the range would comprise toothpaste, tooth brushes and tooth powder. At a later stage, other items, such as mouth wash, may be added to the range.

The 'Binaca Venture' already got off the ground with the company having bagged an export order for tooth-paste worth Rs 2 crores from the Soviet Union. The managing director hopes to be able to further penetrate the East Bloc markets such as Hungary and Czechoslovakia.

As production of tooth-paste is reserved for the small-scale sector, the company plans to farm out production to small-scale units, as it has been doing to service the export orders. Identifying of manufacturing bases has taken some time and to that extent has delayed the launch, explains Mr Sikand.

"Tooth-paste, being a completely new area for us, we took time fitting it into our expansion plans. Besides, we are dependent on a third party for production and have had to locate production bases. We also have to ensure a level of quality which is associated with the company's products".

In general, the managing director is of the view that the demand for house-hold products is growing at a steady pace.

Reckitt has established R and D laboratory for chemicals and aromatic chemicals at Hosur, which is recognised by the department of science and technology. The company also has a plant at Hosur for the manufacture of chemicals and bulk drugs.

The company regularly upgrades its plant and machinery at its factories and Mr Sikand observes that as a result, production levels have been going up over the years. He, however, concedes that there is scope for further improvement in productivity. Wage costs which accounted for around 20 per cent of the expenditure about five yeara ago, have been brought down to about 12 per cent, says the managing director.

The company's sales have grown steadily over the years from Rs 32.85 crores in 1984 to Rs. 40.66 crores in 1985 and further to Rs 48.34 crores in the following year. In 1987, sales stood at Rs. 58.43 crores and last

year the sales jumped to Rs 71.39 crores, Profits before tax too have risen proportionately over the years from Rs. 9.36 crores in 1984 to Rs. 13.58 crores in 1986 and further to Rs. 22.17 crores in 1988.

Earnings per share went up significantly from Rs. 8.7 in 1986 to Rs 13 in the following year. Last year it stood at Rs. 8 on an increased capital after a bonus issue of 1:1. The net worth per share increased to Rs. 42.3 in 1987 from Rs. 32.2 in the previous year. In 1988 it stood at Rs. 26.3 on the doubled capital.

Tamilnadu Dadha Pharmaceuticals Sales Growth Slows Down

MADRAS: Tamilnadu Dadha Pharmaceuticals Ltd. which had shown a big spurt in sales in the recent past, seems to have lost the momentum, as sales show only marginal increases in the last two years.

However, profits and profitability which had suffered a set-back two years ago, have shown a good recovery. The major reason for the spurt in profits is apparently the higher realisation of sales value on the products sold.

The latest published data for the 9 month period ending March, 1989 showed a small increase of 4.55 per cent in sales at Rs. 18.17 crores, compared to the sales of Rs. 17.38 crores during the corresponding period last year. Gross profits improved by 13.33 per cent to Rs. 1.53 crores and net profits by 31.71 per cent to Rs. 0.54 crores during the period. Sales (net of excise duty) during the year ended June, 1988 amounted to Rs. 21.82 crores, just 0.18 per cent higher compared to the previous year. The corresponding increase in the last year was by 9.23 per cent. Over the last four years, sales had expanded by 83.82 per cent. It shows a considerable slowing down in the last two years.

Gross profits, however, recorded a good improvement of 16.13 per cent, from Rs. 1.55 crores in 1986-87 to Rs. 1.80 crores in 1987-88. Net profits (after providing for interest and tax) more than doubled, from Rs. 0.27 crore to Rs. 0.55 crore. Earnings per share also more than doubled, from Rs. 2.45 to Rs. 4.99 Equity dividend was raised from 15 per cent to 16 per cent.

Total capital employed expanded by 38.07 per cent during the year to reach Rs 16.43 crores at the end of June 1988, against a decline of 4.11 per cent recorded in the previous year. Assets nearly doubled in the last four years. The increase in net worth was also appreciable at 62.09 per cent in the latest year. At Rs. 4.49 crores, at the end of June, 1988, net worth nearly trebled in the last four years. The company had raised nearly Rs 76 lakhs by the issue of shares at a premium in January 1985.

In comparison, expansion of gross fixed assets was at a low key. These expanded by only 8.14 per cent in the latest year and by 9.23 per cent in the previous year. Over the last four years, gross fixed assets expanded by 57.63 per cent.

The Drugs (Prices Control) Order, announced in August 1987, has benefited the company considerably as most of its products are in the decontrolled category.

A secrutiny of he last four year's data show that the sales value has by far outstripped the sales volume. The sale of tablets during the last four years increased by 15.77 per cent in terms of volume but by 116.51 per cent in terms of value.

The sale of capsules and liquids declined during the period but their sale value went up by 63.48 per cent and 12.57 per cent, respectively. The volume of the sale of parenterals increased by 59.8 per cent, against an increase of 99.41 percent in value. Bulk drugs which registered a rise of 21.64 per cent in the volume showed a rise of 75.68 per cent in their sale value. However, the excise duty and sales tax contributed only marginally in this rise as these constituted only 5.83 per cent of the gross sales in 1987-88, compared to 3.10 per cent four years ago.

Current assets amounted to Rs 13.58 crores at the end of June 1988. Resources mobilised through current liabilities amounted to only Rs. 5.54 crores, leaving working capital gap of Rs. 8.04 crores. Bank credit has gone up considerably, amounting to Rs. 5.50 crores in 1987-88 (including term loan). The current ratio appears unfavourable.

The net return on net worth has improved considerably, from 9.75 per cent to 12.25 per cent. Although gross return on the total capital showed a decline, gross return on sales showed a good rise. The company also issued bonus shares in the ratio of one to two.

After the fall in the share price following the bonus issue, the price has recovered to Rs. 47.00. The exbonus earning rate comes to 7.09 per cent.

Bayer (India) Increases Turnover

BOMBAY: During the 15 month period, January 1988 to March, 1989, Bayer (India) increased its turnover to Rs. 162.3 crores, up 45 per cent over 1987. As in the past, the major contribution came from agrochemicals and rubber chemicals divisions. Following receipt of long-awaited price increases under the Drug Price Control Order 1987, combined with effective cost saving measures, the pharmaceuticals division made a marginal profit.

The directors have recommended a higher dividend of 30 per cent for the period against 16 per cent paid last year.

For the company 1988-89 was period of encouraging growth. The profit of the company before provision for depreciation and taxation has gone upto Rs. 17.71 crores from Rs. 12.03 crores. After taking into consideration the provisions for depreciation (Rs. 2.78 crores against Rs. 4.14 crores) and taxation of Rs. 5.6 crores against Rs. 3.48 crores and after adjustment of income tax for the earlier year Rs. 73 lakhs, the net profit during the period is at Rs. 9.25 crores against Rs. 4.41 crores, higher by 110 per cent.

Glindia Seeks Change In Name To Glaxo India

NEW DELHI: The erstwhile Glaxo Laboratories, which changed its name to Glindia Ltd., a few years ago, is proposing to change its name yet again to Glaxo India Ltd., subject to the approval of the Union Government.

The company has given notice for an extraordinary general meeting (EGM), in Bombay, on June 16 to consider and, if thought fit, to pass with or without modification a special resolution that the articles of association of the company be altered pursuant to Section 31 of the Companies Act, 1956, by the insertion of the new Article 3 with a marginal note to that effect. Also, the shareholders are to resolve that on the Centre's approval—the change in the name of the company becoming immediately complete and effective—the new name be substituted for the existing name wherever it appears in the memorandum and articles of association of the company.

Evidently, the saying 'what's in a name' does not hold good any more, especially in busines. What count and goes a long way in increasing the business propects is the goodwill earned over the years through an established trade name. The Indian company has veered round to the view that the inclusion of the word "Glaxo" instead of 'Glindia' would do just that.

Accordingly, the Indian company has entered into a licence agreement with Glaxo Group Ltd., UK, which is the exclusive owner of the Glaxo trade mark and also holds 40 per cent of the domestic company's equity. The agreement gives a right to the Indian company to use the word Glaxo in its corporate name and its products provided that the UK firm is empowered to call upon the domestic company to change its name by deleting the word from its name in certain eventualities. Even earlier, the company had been granted registered user rights for several trade marks including Glaxo under various agreements from time to time.

One of the main objectives of the change in corporate name is that it would fortify the image of the company and of its pharmaceutical products thus providing long-term benefits to the domestic company. It would not only identify the company as a member of the worldwide Glaxo family, but also be of considerable advantage in export activitities in and in obtaining state-of-the-art technology.

In a note to the shareholders, the Glindia board has contended that it would be in the best interests of the company to be known as Glaxo India Ltd. as Glaxo is the acknowledged and renowned international name for high quality products, which have a proven reputation throughout the world for dependability, safety and effectiveness. The UK company has emerged as a pharmaceutical group of global stature not merely in terms of size and diversity of operations but also in its contribution to research and technology and in the introduction of new products.

The Registrar of Companies has informed the company that the new name should be registered within a period of six months from April 13,1989.

Colgate Bonus Shares

BOMBAY: The board of directors of Colgate-Palmolive (India) has announced issue of bonus shares on a one-for-one basis besides a final dividend of 9% making a total of 45% on the enlarged capital for the year ended December 31, 1988, as against 52% paid for the previous year. The board has also declared payment of an interim dividend of 20% for the current year.

The Company has fared very well with higher turnover, profits and margins. Sales have amounted to Rs. 229.40 crore against Rs. 182.21 crore in the previous year, a rise of about 26%, and gross profit has advanced by 44% to Rs. 46.03 crore from Rs. 32.48 crore, according to the preliminary figures.

After depreciation (Rs. 66 lakh against Rs. 58 lakh) and taxation (Rs. 24.13 crore against Rs. 15.09 crore), there is a net profit of Rs 21.24 crore compared to Rs. 15.09 crore of 1987.

Out of this, the year's total distribution by way of dividend will absorb Rs. 7.08 crore (Rs 6.29 crore). General reserve number one gets Rs. 2.12 crore (Rs. 1.51 crore) and general reserve number two Rs. 12.04 crore (Rs. 7.29 crore).

Rallis India

BOMBAY: Rallis India has turned in encouraging working results for the 11-month period ended March 31 last with higher sales and profits compared to the previous 12 months.

The company has reported sales and other income of Rs. 297 crore against Rs. 262.90 crore previously and a gross profit of Rs. 11.77 crore against Rs. 9.67 crore, according to the unaudited preliminary figures.

After providing Rs. 2.87 crore (Rs. 2.08 crore) for depreciation and Rs. 2 crore (same) for taxation, there

is a net profit of Rs. 6.90 crore compared to Rs. 5.59 crore of 1987-88. It may be noted that last year's profit figure included Rs. 1.35 crore as profit on sales of assets.

According to Mr. D.S. Seth, chairman, these results are the highest ever achieved by the company, thanks largely to satisfactory performance of the agro-chemicals division.

Eskayef Fares Well

BOMBAY: Eskayef Ltd., has fared satisfactorily during the 16-month period ended March 1989. Sales are up to Rs 92.52 crores from Rs. 62.77 crores and the gross profit to Rs. 13.64 crores from Rs. 10.27 crores in the previous year. On annualised basis, sales are higher but the gross profit is maintained.

After depreciation (Rs. 46.76 lakhs against Rs. 72.47 lakhs), and taxation (Rs. 444 lakhs against Rs. 376 lakhs), the net profit is worked out to Rs. 873.06 lakhs compared to Rs. 578.56 lakhs in the previous year. The net profit is, however, better on an annualised basis.

Chinar Pharmaceuticals

NEW DELHI: Chinar Pharmaceuticals, located at 375, Udyog Vihar, Phase-II, Dundahera, Gurgaon (Haryana), is small-scale unit which would put a number of industrial giants to shame. The plant housed in over 4,000 sq. ft. of first class RCC construction, with built-in power generator and electric tubewell is equipped with the latest production and quality control facilities in the field of drug formulations. The strength of the unit lies in its highly professionalised management, uncompromising adherence of quality and an unflinching thrust towards consumer satisfaction.

The unit started production in 1985 and currently with an investment of around Rs. 15 lakhs and employing some 15 workers, its turnover has touched Rs. 1 crore. Amongst the formulations presently under production are antibiotics, antibtubercular drugs, antiamoebics and premenstrual syndrome formulations and the management is continuously developing new formulations. While its major marketing thrust is directed towards medical institutions, CGHS, ESI, DGS and D hospitals, it has also set up outlets in some important cities throughout the country.

The venture was originally conceived by Dr. Pradeep R. Mehendiratta, a management expert with years of administrative experience at top levels. He chose pharmaceutical line because his son Deepak had done his graduation in pharmaceutical science. The unit was set up as a partnership between Dr. Mehendiratta, his son Deepak, and daughter Purnima. Deepak after obtaining his B.Pharm. degree did his MBA from the US and Purnima did her MBA specialising in marketing.

Management and marketing experts at the top ensured that the project report was prepared with meticulous care and precision. Dr. Mehendiratta's personal contacts in the US had been extremely helpful in extending all the technical advice sought by him. The management also enlisted the support and guidance from some of the leading doctors in Delhi. The result has been a steady planned growth of the unit and a well deserved reputation for quality and business ethic among its customers. The unit is also negotiating with some US pharmaceutical producers for collaboration for certain new formulations. Young Deepak, virtually running the unit, attributes the success of the venture to the management's basic theme of striving for excellence.

Chemicals, Cosmetics Exports Cross Rs. 1200 Cr. Target

BOMBAY: Exports of chemicals, pharmaceuticals and cosmetics in 1988-89 touched a record figure of Rs. 1247 crore surpassing the target of Rs. 1200 crores fixed by the Basic Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council for the year.

The export of these products during 1988-89 recorded a growth rate of 59 per cent over the previous year. In 1987-88, the export of chemicals, pharmaceuticals and cosmetics was only Rs. 783.37 crores.

Two important groups of items, namely basic drugs and formulations and dyes and dye intermediates, were mainly responsible for the quantum jump in exports.

Export of basic drugs and formulations registered a growth of over 75 per cent at Rs. 400 crores in 1988-89 from the level of Rs. 222.8 crores achieved in the previous year. Dyes and dye intermediates went up by 87 per cent at Rs. 401.60 crores in 1988-89. The export of these items was only Rs. 214 crores in 1987-88.

Another group of items which recorded a 62 per cent growth rate during 1988-89 was inorganic and organic chemicals. The export of these items in 1988-89 grew to Rs 149.41 crores from Rs. 92.17 crores in the previous year. A similar increase was recorded in the export of soaps, detergents and toiletries during 1988-89. Their exports touched Rs. 140 crores in 1988-89 as against Rs. 85.57 crores in the previous year.

The growth in the export of items like agarbattis and essential oils was however marginal.

On the other hand there has been a drop in the export of items like opium, psyllium husk and crude drugs. The export of these products fell to Rs. 61.24 crores duing 1988-89 from Rs. 77.36 crores in the previous year.

Standard Medical

BOMBAY: With more than a four fold increase in its total income, Standard Medical and Pharmaceu-

ticals Ltd. (SMPL) has registered an impressive performance for the 18 month period ended March 1989.

The total income of the company rose sharply from Rs. 530.22 lakhs for the year ended September 1987 to Rs. 2349.45 lakhs, a growth of 195 per cent over the earlier year on annualised basis. The lease and hire purchase income increased to Rs. 581.86 lakhs (Rs. 336.28 lakhs). The diagnostic centres receipts also increased to Rs. 560.80 lakhs from Rs. 122.54 lakhs. Sales from the bulk drug unit, which was merged with the company during this accounting period, amounted to Rs. 934.24 lakhs.

The gross profit was higher at Rs. 263.88 lakhs from Rs. 172.68 lakhs. However, mainly because of the impact of heavy initial expenditure including depreciation claimed by the new diagnostic centres at Pune, Bangalore and Calcutta, the net profit was lower at Rs. 54.57 lakhs.

The new diagnostic centres are doing well and are consistently recording a growth of over 50 per cent in their daily income. The company expects its bulk drug division to register a further jump in its sales and profits both in the domestic and export markets.

SOL Pharma Increases Sales

BOMBAY: SOL Pharmaceuticals has achieved a turnover of Rs. 12.81 crores in the nine month ended March, 1989, against Rs. 13.29 crores in the 12-months period ended June 1988, an increase of about 30 per cent on an annualised basis.

The company earned a profit of Rs. 78.54 lakhs against Rs. 65.65 lakhs before tax and depreication, a jump of 60 per cent. After providing for depreciation Rs. 10.82 lakhs against Rs. 13.03 lakhs and taxation Rs. 10.75 lakhs against Rs. 3.34 lakhs, after tax profit is Rs. 56.97 lakhs against Rs. 49.28 lakhs.

With the launching of new formulation, increased support from bulk drug activity and a further thrust on export market, the growth performance and returns look bright for the years to come.

E. Merck (India) Reports Encouraging Results

BOMBAY: E. Merck (India) has reported encouraging performance during the current year. Sales during the first five months have registered a growth of 27 per cent from Rs. 17.22 crores in 1988 to Rs. 21.85 crores during the corresponding period in the current year, according to Mr. S.N. Talwar, Chairman of the company.

Addressing shareholders at the company's 22nd annual general meeting held recently, he said that the first phase of the pharma expansion project in Goa would be completed this year. The diagnostics range of products was also being expanded, he added.

He said that the company's turnover as well as profit have gone up mainly due to the optimum utilisation of resources and improved efficiency of operations.

New Drug Launched By Lederle

BOMBAY: Lederle, the pharmaceutical division of Cynamid India Ltd, has launched, for the first time in India, a new broad-spectrum antibiotic, cynomycin. The drug is an original research product of Lederle.

According to a company press release, cynomycin is already marketed in over 50 countries the world over. The company has carried out extensive clinical trials in India and will manufacture the drug at its factory at Valsad in Gujarat.

Cynomycin will provide Indian doctors a superior alternative to penicillin, ampicillin, cephalosporins, norfloxacin and other antibiotics against susceptible organisms, the press release adds.

Denis Chem Lab. Reports Improvement

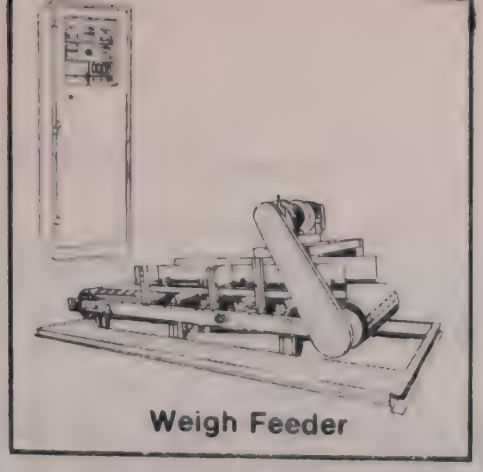
BOMBAY: Denis Chem Lab, has reported all-round improvement in its working results for the 15-months period ended March 1989. The directors have recommended a maiden dividend of 12 per cent.

The total income during the period amounted to Rs. 348.31 lakhs against Rs. 231.06 lakhs.The company earned a gross profit of Rs. 42.81 lakhs against Rs. 36.48 lakhs before providing Rs. 8.19 lakhs against Rs. 7.68 lakhs for depreciation, Rs 18.35 lakhs against Rs. 16.84 lakhs for interest, and Rs. 2.60 lakhs against Rs. 1.30 lakhs for taxation. The net profit after provision amounted to Rs. 13.67 lakhs against Rs. 10.65 lakhs.

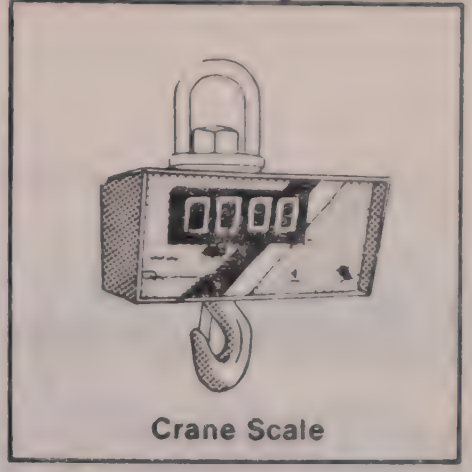
The company's intravenous solution plant has achieved about 85 per cent capacity utilisation. As part of its expansion plan it intends to substantially expand and modernise its present production capacity of I.V. solutions. It is also planning to diversify into the manufacture of small volume injectables.

The company intends to raise Rs. 10.50 lakhs by offering 1.05 lakh equity shares on rights basis in the ratio of 1:4 at par. The balance of the project cost will be met through internal accruals and cash subsidy from the State Government. It has also approached financial institutions for term loans.

Top Loading Balance

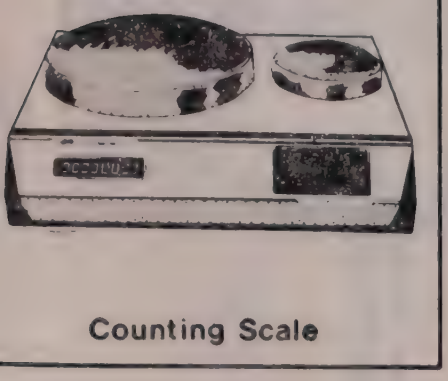


Weigh Feeder



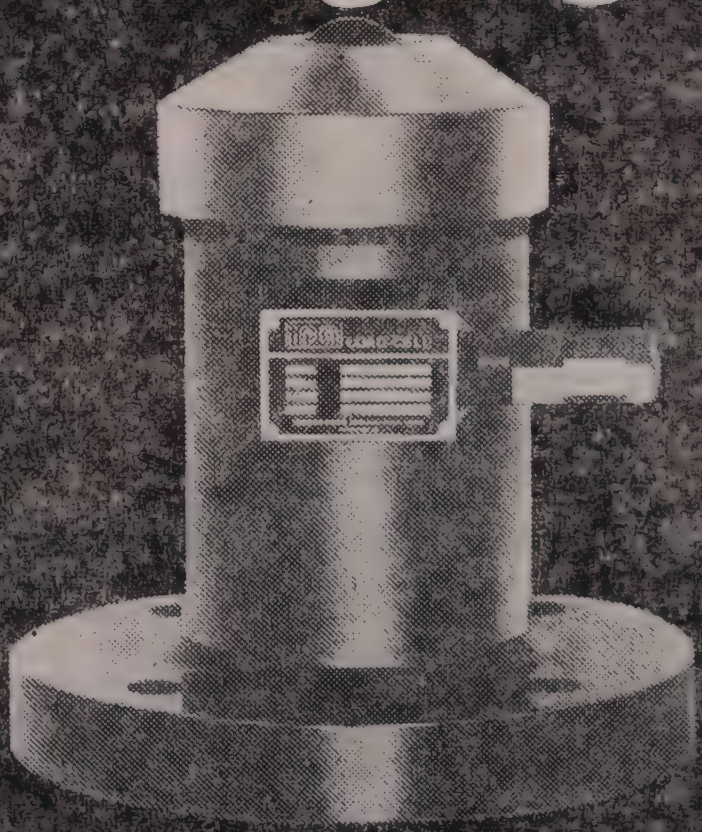
Crane Scale

Godown Scale



Counting Scale

The House of Electronic Weighing



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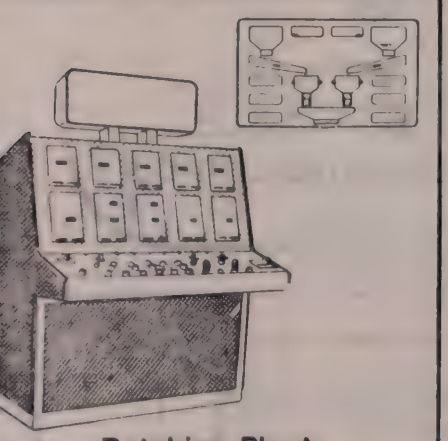
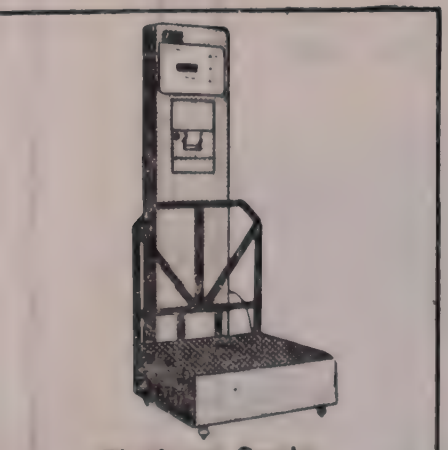
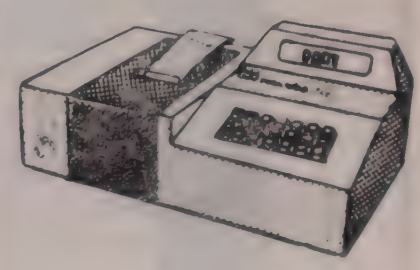


Batching Plant

Lorry Weighbridge

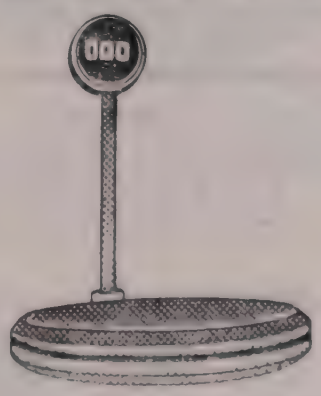


Platform Scale

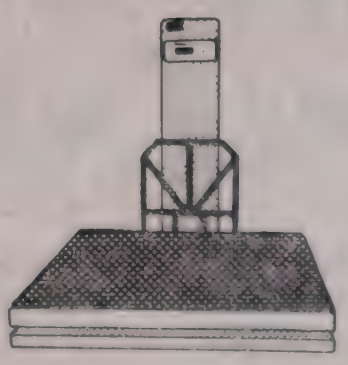


Weigh Print

Tank & Hopper Weighing Systems

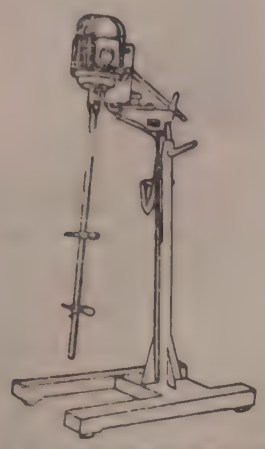


Counter Scale

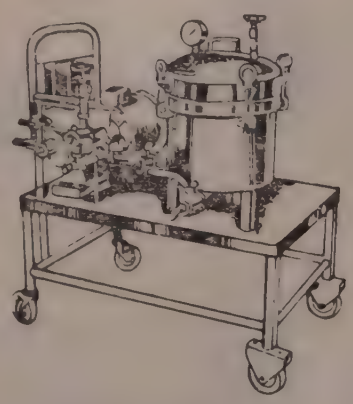


Dormant Scale

Belt Weighers



SELF SUPPORTED STIRRER



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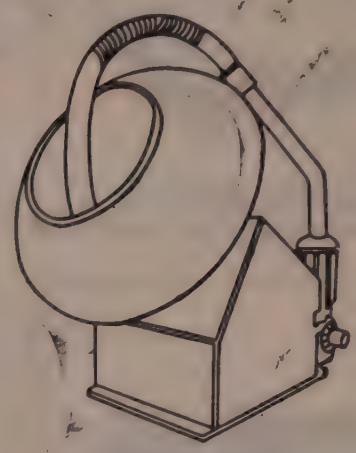
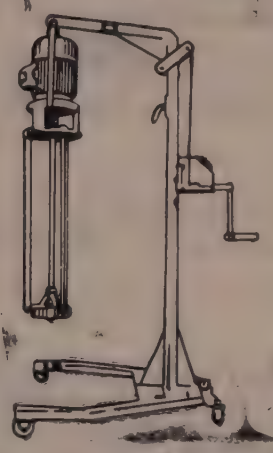


COATING PAN



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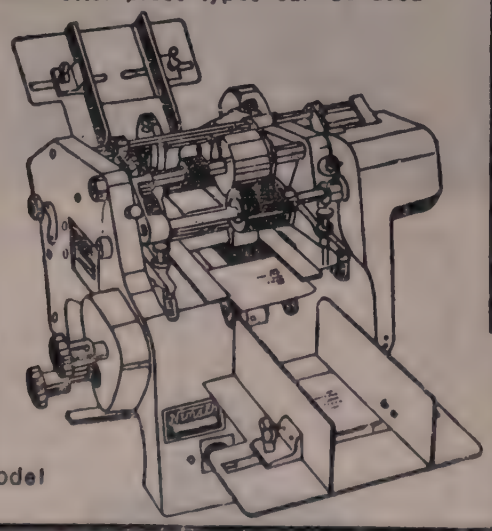
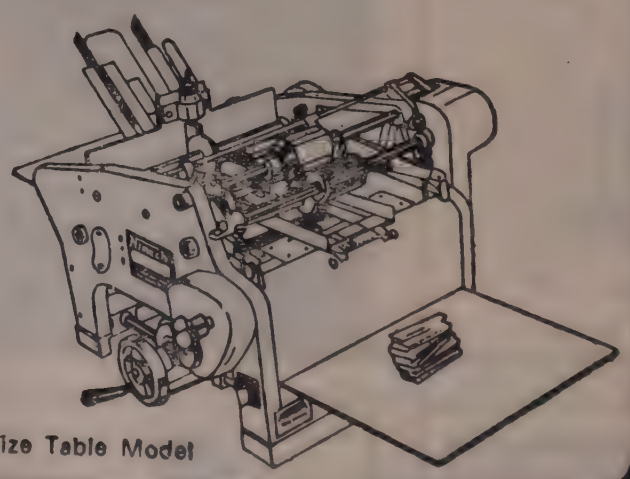


* Size Table Model

NIMACH BRAND HIGH SPEED CARTON PRINTER MACHINE TYPE A U 2

* Three Speeds 125/180/250 carton/min
* Size of cartons 13" x 7" Max. 3 1/2" x 2" Min.
* Plain & Locked botton cartons & Catch cover can be printed
* Stereos can be used.



* Size Table Model

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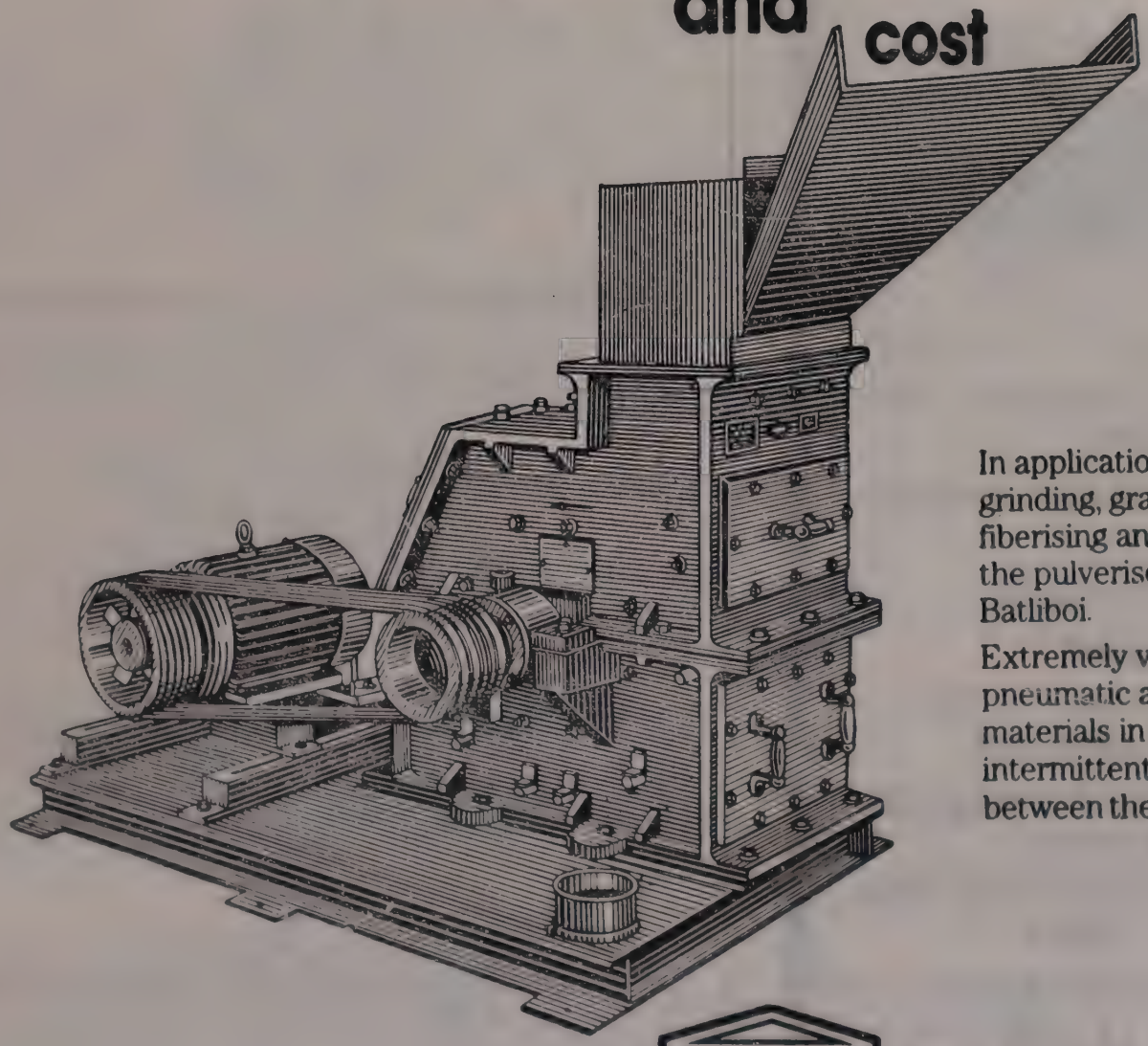

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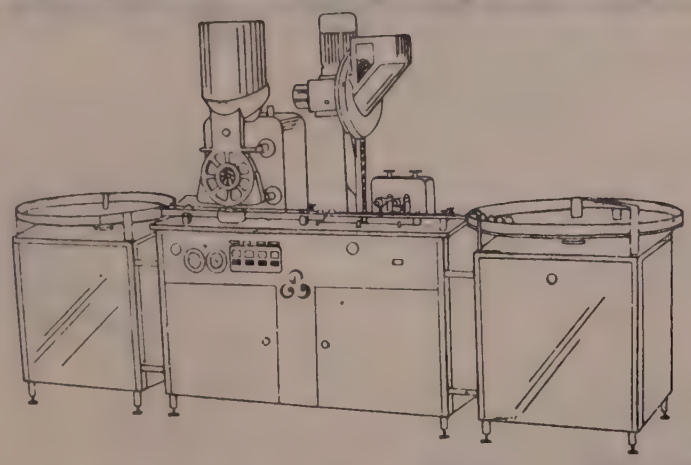

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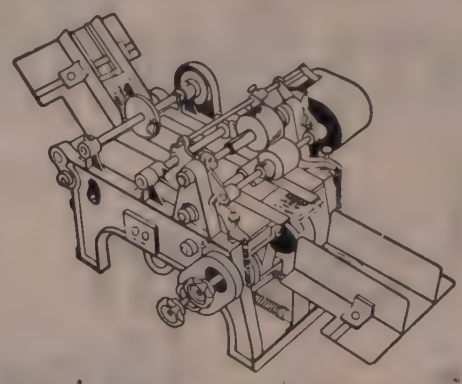

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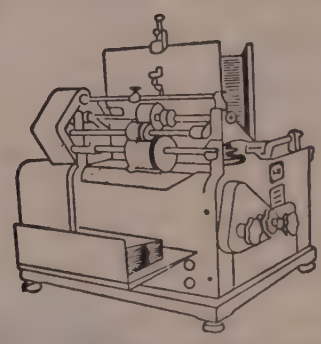
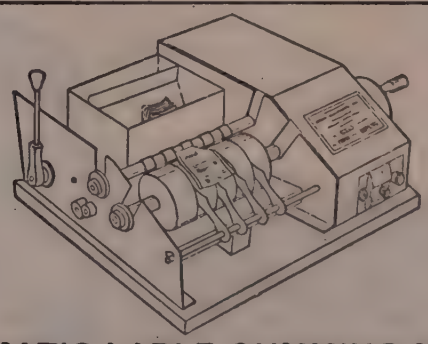


HIGH SPEED CARTON OVER PRINTING MACHINE
MODEL JCP-250
OUTPUT : 6000 TO 12000 CARTONS/HOUR



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NEWS FROM ASSOCIATIONS

Drug Industry, Trade To Meet To Settle Discounts Issue

BOMBAY : Drug manufacturers and traders have decided to hold talks to resolve the dispute on trade discounts, following a suggestion by the government.

At the meeting, which held on July 21 in Bombay, the industry was represented by the Organisation of Pharmaceutical Producers of India (OPPI) and the Indian Drug Manufacturers' Association (IDMA) while the All-India Organisation of Chemists and Druggists (AIOCD) represented the trade.

Though no agenda had been drawn up it is clear that the meeting had been arranged to bring about an amicable settlement to the trade discount issue without the need for government intervention.

The industry has been maintaining that the government has already allowed enough trade discounts to retailers under an order issued on March 22, 1988 within the framework of the Drug (Price Control) Order, 1987. The trade on the other hand has been agitating for a specific trade margins for wholesalers by the drug companies.

AIOCD sources said that the March 22 order specifies a retail trade margin of 16 per cent excluding excise duty but has ignored the trade discount for wholesalers. The absence of a wholesalers' discount is a retrograde step as the government had in the earlier DPCOs provided a 2 or 3 per cent trade margin to this section of the trade.

AIOCD has also been agitating for the reversal of the order as it is unhappy with the exclusion of excise duty in the computation of the 16 per cent trade margin for retailers,

The drug industry on the other hand, feels that the 16 per cent retail trade margin has already placed a heavy burden on manufacturers and a further discount for wholesalers will made it impossible for the industy to absorb the cost hikes.

The industry pointed out that individual companies reach agreements with their stockists under which the latter are entitled to certain discounts. The producers are in favour of continuing with this system where stockists on an average enjoy a discount of over 5 per on formulations marketed.

The trade, however demanded a wholesalers' discount of 8 per cent with the 1983 price as the base. The association said that while IDMA has conceded this demand the multinational drug producers represented by OPPI have taken a tough stand against the wholesalers' demand.

AIOCD is also piqued at the stand taken by the committee appointed to resolve the trade margin dispute. The committee headed by Dr. Z.A. Bhatty of the National Council of Applied Economic Research (NCAER) issued a 40-page questionnaire to drug manufacturers and—wholesalers and retailers. The association said that this survey was aimed at dividing the retail and wholesale trade and instructed its members to boycott the survey.

The Bhatty committee was, therefore, unable to complete its work and there was no sign of the dispute being resolved.

Since the government has not taken any meaningful step to break the impasse the trade and industry have been left with no alternative but to come to the negotiating table.

OPPI-IDMA Joint Meeting With Secretary C & PC

BOMBAY : OPPI and IDMA jointly had a half day meeting with Mr. M.S. Gill, Secretary and Mr. R.S. Mathur, Joint Secretary and Development Commissioner (Pharma Industry), Department of Chemicals & Petrochemicals, here recently.

About 70 representatives of both the Associations attended the meeting. The main focus of discussion was speedier implementation of DPCO 1987 and pricing of bulk drugs and formulations. Dr. S. Agarwala, President, OPPI, made a presentation on the current status and problems of the industry. Mr. N.I. Gandhi, President, IDMA, in his welcome address, dealt with the urgent issues facing the industry.

Mr. Gill and Mr. Mathur comended the coming together of both the Associations on one platform to present the industry's point of view instead of OPPI and IDMA putting forward separate and at times conflicting views. The officials promised to look into the industry's problems with sympathy and understanding.

Pharma Industry In Eighth Plan—Industry's Submission

BOMBAY : OPPI jointly with IDMA has developed a paper on demand projections for bulk drugs and formulations and investment required to meet the projected demand in the 8th Five-Year Plan period, 1990-91 to 1994-95. The paper, prepared by a joint working group consisting of experts drawn from both the Associations, was recently submitted to the working group set up by the Planning Commission for the 8th Five-Year Plan.

Mr. M.S. Gill, Secretary, Department of Chemicals & Petrochemicals, is the Chairman of the working group.

The paper has estimated that total investment called for to achieve a production level of Rs. 6,610 crores (bulk drugs production of Rs. 1349 crores × bulk drug to formulation ratio of 1:4.9) in 1994-95 is Rs. 2,200 crores as against the present investment of Rs. 750 crores. There is therefore a gap of Rs. 1,450 crores between the investment of Rs. 750 crores at the end of 1987-88 and the total investment required at the end of 1994-95. However, taking into account the idle capacity, estimated at one-third of the total, and assuming full utilisation of capacity by the year 1994-95, the additional investment would be Rs. 1,200 crores (Rs. 1,450 crores minus Rs. 250 crores).

The industry working group has noted that the annual average growth rate in production of formulations has declined from 32.5% in 5th Plan to 10.4% in the 6th and 8.8% in the 7th Plan. It anticipates that the 7th Plan growth rate will be maintained in the 8th Plan. On the basis of this assumption it has estimated that the per capita consumption per annum will increase from Rs. 52 in 1989-90 to Rs. 71.3 in 1994-95. This is indicated in the table below :

Per capita consumption

Year	Population (millions)	Value of Production of Formulations (Rs. in crores)	Per Capita Consumption (Rs.)
1979-80	675	1,150	17.0
1984-85	751	1,827	24.3
1989-90	832	2,800*	33.6
1989-90	832	4,329**	52.0
1990-91	850	4,710**	55.4
1991-92	869	5,124**	59.0
1992-93	888	5,575**	62.8
1993-94	908	6,066**	66.8
1994-95	928	6,610**	71.3

* At 1979 prices
** At 1989 prices

Even this modest increase in per capita consumption and wider coverage of the population is a challenging task for the industry. However, given a favourable framework of growth, production could be increased to meet the projected demand. Several suggestions have been made in the paper to improve the policy framework. It has emphasised that the industry has reponded to the needs of the country during a regime of pragmatic policies by gearing up both production and investment as it did during the 5th Plan period.

Annual General Body Meeting Of Indian Hospital Pharmacists Association—Orissa State Branch

BERHAMPUR : The Indian Hospital Pharmacists' Association organised a Lecturer on Hospital Pharmacy which was held at the Auditorium of Ronald Institute of Pharmaceutical Sciences, Berhampur rcently.

The programme was started with a regional T.V. picture. It was followed by a traditional opening song by Miss. Valsa and inviting to guests to speak by Mr. P. Suresh.

The meeting was presided over by Sri J.N. Das. The Chief-Speaker, Mr. M.E. Bhanoji Rao in his lecture stressed on the importance of hospital Pharmacy with a back-ground history for the same. Mr. P. Suresh in his lecture narrated on the various aspects of hospital Pharmacy with emphasis on other related aspects. Mr. B.B. Nayak in his address emphasised on the duties and responsibilities of Pharmacists in this noble profession.

The Lecture was followed by the Annual General Body meeting of Indian Hospital Pharmacy Association (IHPA) which was also presided over by Sri J.N. Das. Mr. P. Suresh presented the Annual Report of the Branch in absence of the Secretary for the year 1988-89 along with the expenses statement with the request of the President. The following resolutions, were unanimously adopted during the open session of the Annual General Body meeting of IHPA.

Sri Das in his Presidential address stressed the need to improve and strengthen the Association with all possible efforts.

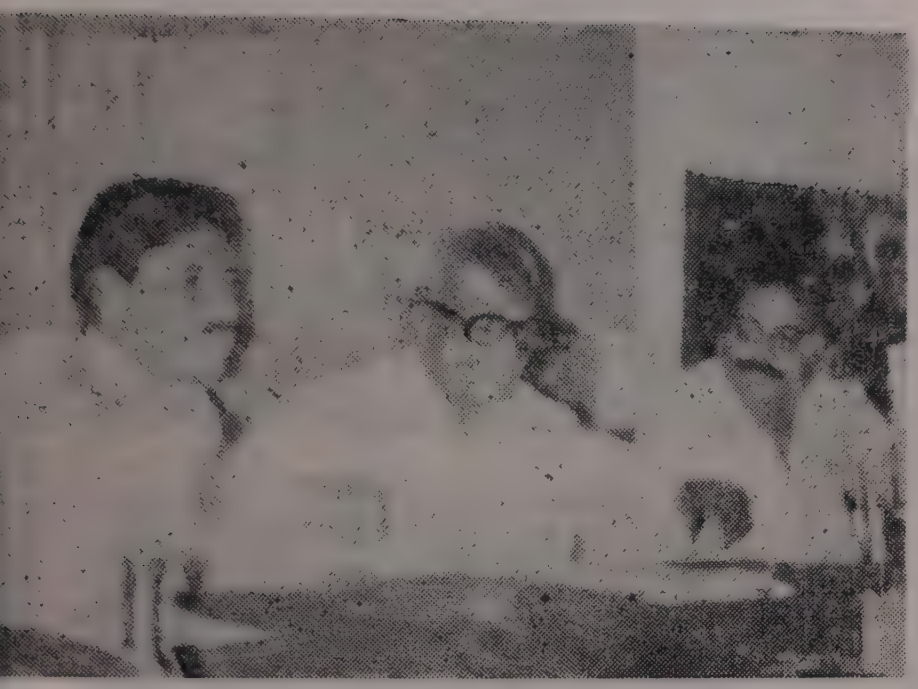
The meeting was terminated with vote of Thanks by Mr. P. Suresh.

Resolutions Adopted at the meeting are :

No: (1)—It seems that some vested interests are keen to utilise the Government of Orissa to get the West Bengal registered Pharmacists registered in Orissa, on reciprocal basis, as evident from the proceedings of the Orissa Drugs Advisory Committee held at Bhubaneswar on 8.6.1989. Thousands of people with no Pharmacy education or experience were registered in West Bengal Pharmacy Council and the matter is now under investigation by a Commission, appointed by the West Bengal Government. The matter is also under correspondence between the above two State Pharmacy Councils. The Pharmacy Councils are autonomous bodies and the State Pharmacy Councils are paramount bodies to decide on Registration of candidates as per rules in vogue.

It is evident that the terms of reference of the State Drugs Advisory Committee is to advise the State Government specially on the technical matters arising out of enforcement of Drugs and Cosmetics Act, 1940 and Rules thereunder. It has no scope to appoint a sub-committee to go into the matter of Registration of Pharmacists which clearly falls under the provision of Pharmacy Act, 1948. As such the State Drugs Advisory Committee has no locus-standi in the matter.

It is therefore resolved that the State Government of Orissa as well as the members of the Sub-Committee so



Annual Conference of the IHPA Orissa State Branch held at Berhampur on 18-6-1989. (*L to R*) *Shri P. Suresh, Secretary, Shri J.N. Das, President, Shri M.E. Bhanoji Rao, Vice President of the Association.*

appointed, by the State Drugs Technical Advisory Committee be refrained from taking any action in the matter, in the interest of the health of the people as well as the profession of Pharmacy.

No. : (2). The Section 42 of the Pharmacy Act, 1948 has taken automobile enforcement in the Country since 1.9.1984. Such a cognizable legal provision of the Act, is neither implemented till date in proper spirit nor it has protected the professional interest of the Pharmacists.

It is therefore resolved to request the Central Government and the Pharmacy Council of India to issue necessary instructions to the State Governments to implement this Section of the Act regidly and provide the State Pharmacy Councils with necessary funds in order to protect the health of the people which is being endangered by exposure to unqualified and inexperienced persons.

No. (3). Inspite of provisions in Pharmacy Act, 1948, the State Pharmacy Councils do not appoint Inspectors on the plea that there is paucity of funds to meet the expenses. The State Governments also do not take any action to meet the situation nor frame rules as required under Section 46 of the said Act. For the purpose of inspection of Pharmacy Colleges and Schools, the Pharmacy Council of India has some honorary Inspectors. Accordingly honorary Inspectors by appointed to inspect the premises where drugs are dispensed. If Pharmacy graduates are not available, the question of appointment of experienced registered diploma holders in Pharmacy may also be considered.

It is therefore resolved that Government be requested to appoint honorary Inspectors of State Pharmacy Councils under Section 26-A of the Pharmacy Act, 1948 and the same be notified in the Gazette in exercise of the powers vested with the State Government under section 46 of the Pharmacy Act, 1948.

No: (4). Resolved that the funds of the Associaion be kept in postal Savings Bank at Berhampur and the Executive Committee be authorised to frame rules for is operation and amend the rules if so required.

No: (5). It is resolved that the heads of the Pharmacy training Institutions in Orissa be requested to convince and persuade the Pharmacy students of their Institutitions to be the Life-members of the INDIAN HOSPITAL PHARMACISTS ASSOCIATION by paying the subscription of Rs. 150/- each. The Life-member of this Association will get a bi-monthly magazine of the Association free of cost life-long and they will acquire adequate knowledge in the field of Pharmacy which will be far beneficial to them in the future.

The heads of the Institutions may also be requested to realise this subscription at the time of admission of the candidates into this course.

No: (6). It appears that some of the existing Pharmacy Institutions in the State of Orissa are not functioning properly. As such it has been resolved to request the Government of Orissa to initiate necessary action for the healthy growth and smooth functioning of existing Pharmacy Institutions in this State.

No: (7). It has been observed that a quite a good number of Pharmacy Institutions offering Diploma course in Pharmacy in the State of Orissa have come up and some others are in process. If this fast rate of growth of Pharmacy Institutions with hardly any quality of teaching remains unchecked, a day may come when lot of qualified Pharmacists will remain jobless after the turn of the Century.

Hence it has been resolved to request the State Government not to grant permission for the opening of any more Diploma in Pharmacy Institutions.

No. (8). As there is no M.Pharm. Institution in the State of Orissa, it has been resolved to request the State Government and the Universities of this State for initiating humble efforts for the opening of M.Pharm. Institutions (Course) in Orissa.

B.V. Patel Education Trust Symposium

AHMEDABAD : Shri B.V. Patel Education Trust is organising an International Symposium on "Innovations in Pharmaceutical Sciences and Technology" from 27 to 29th October, 1990 at Ahmedabad to mark the inauguration of Shri B.V. Patel Pharmaceutical Education and Research Development Centre. The Centre will provide facilities and offer opportunities to pharmacy teachers and pharmacists to attain excellence in their chosen spheres of activity. It may also cater to the needs of higher education and advanced research in some high priority areas.

The programme will comprise plenary and special invited lectures, workshops, business sessions and a few contributed papers for oral and poster presentation. An exhibition on current developments will also be arranged. Interested participants may write for details to Prof. H.L. Bhalla, (Symposium Co-ordinator) Bombay College of Pharmacy, Kalina, Bombay-400 098 (India).

Shri I.A. Modi (Hon. Secretary, Shri B.V. Patel, Education Trust) Managing Director, Cadila Laboratories Ltd. Manager, Ahmedabad-380 008 (India).

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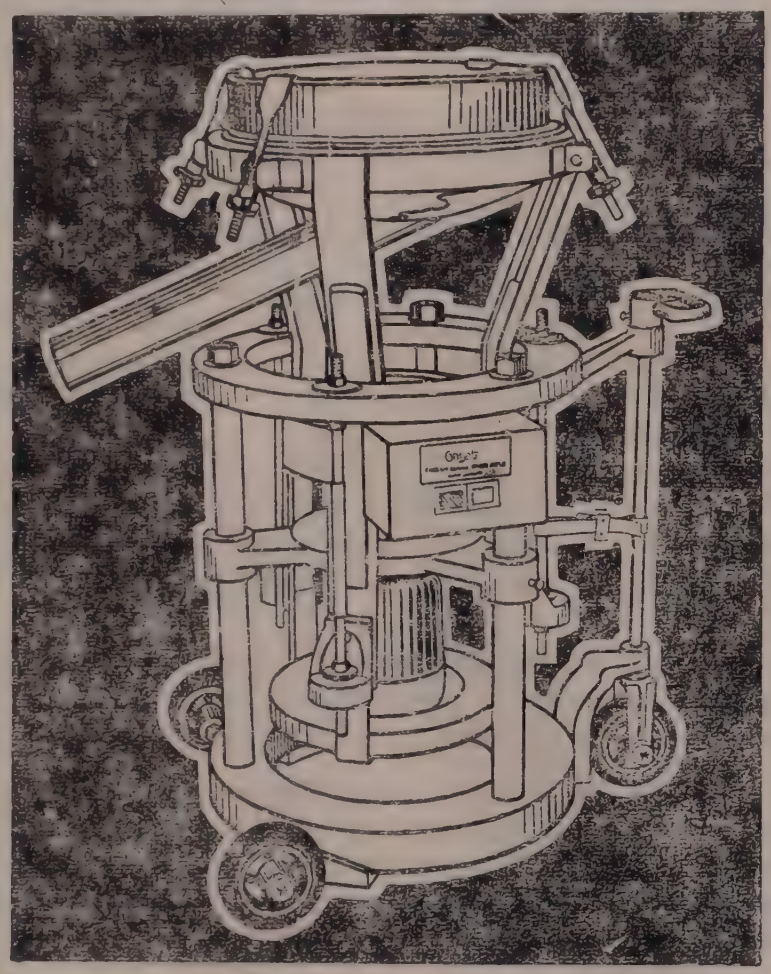

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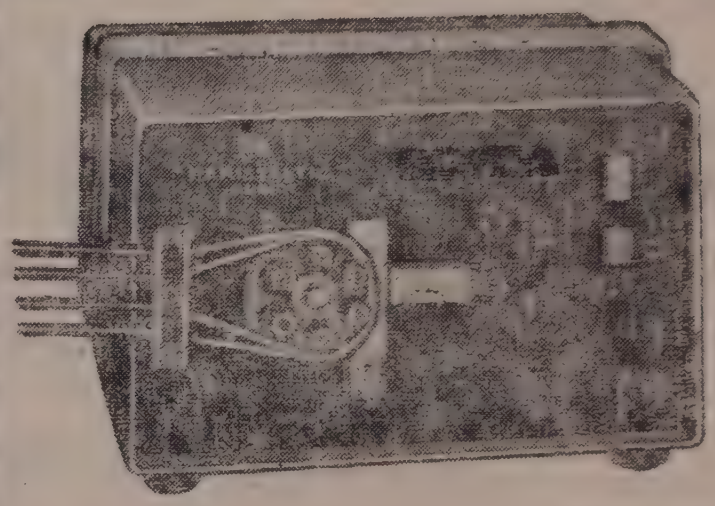

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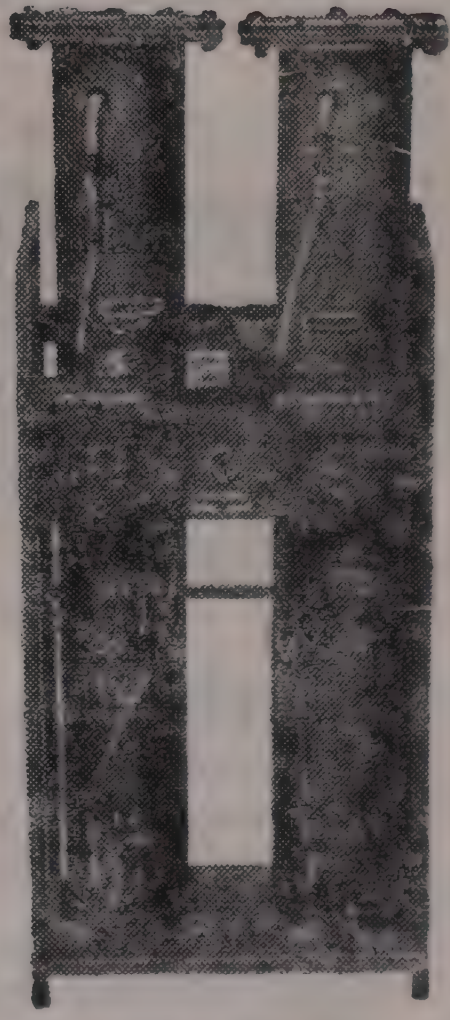

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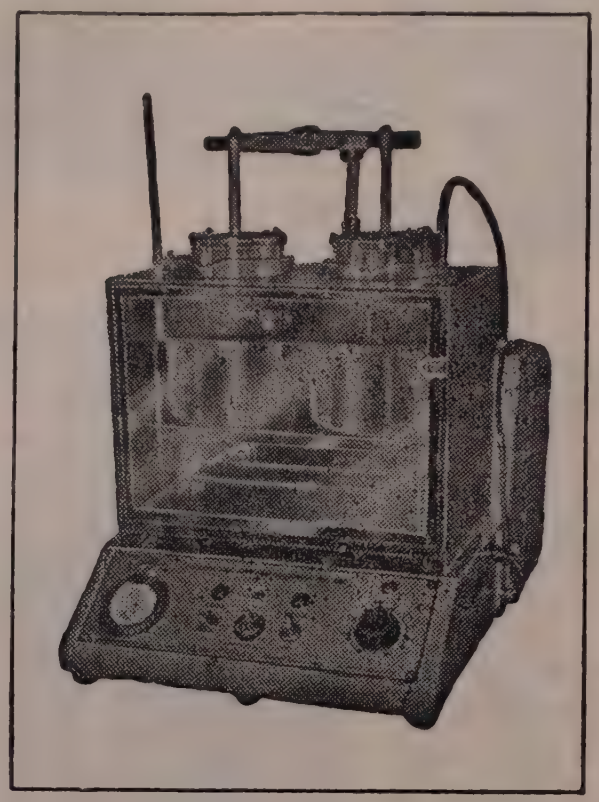

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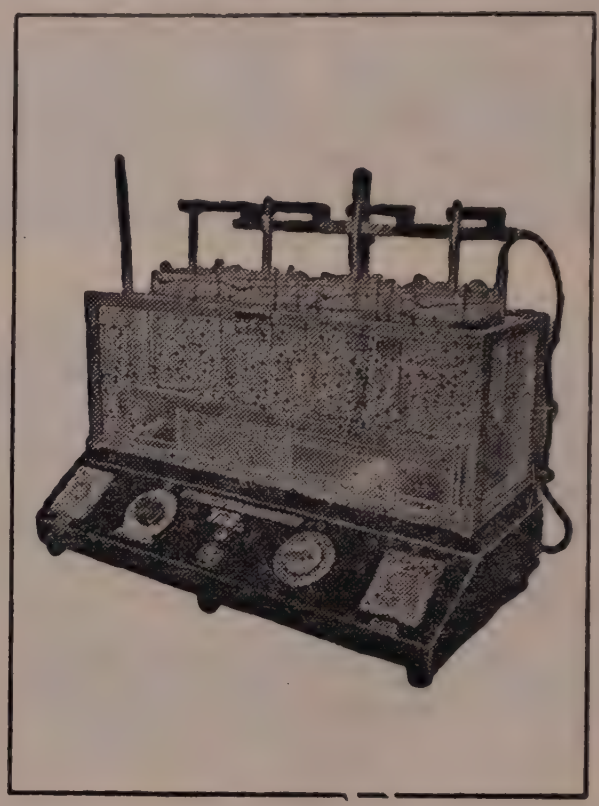

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THERMONIK

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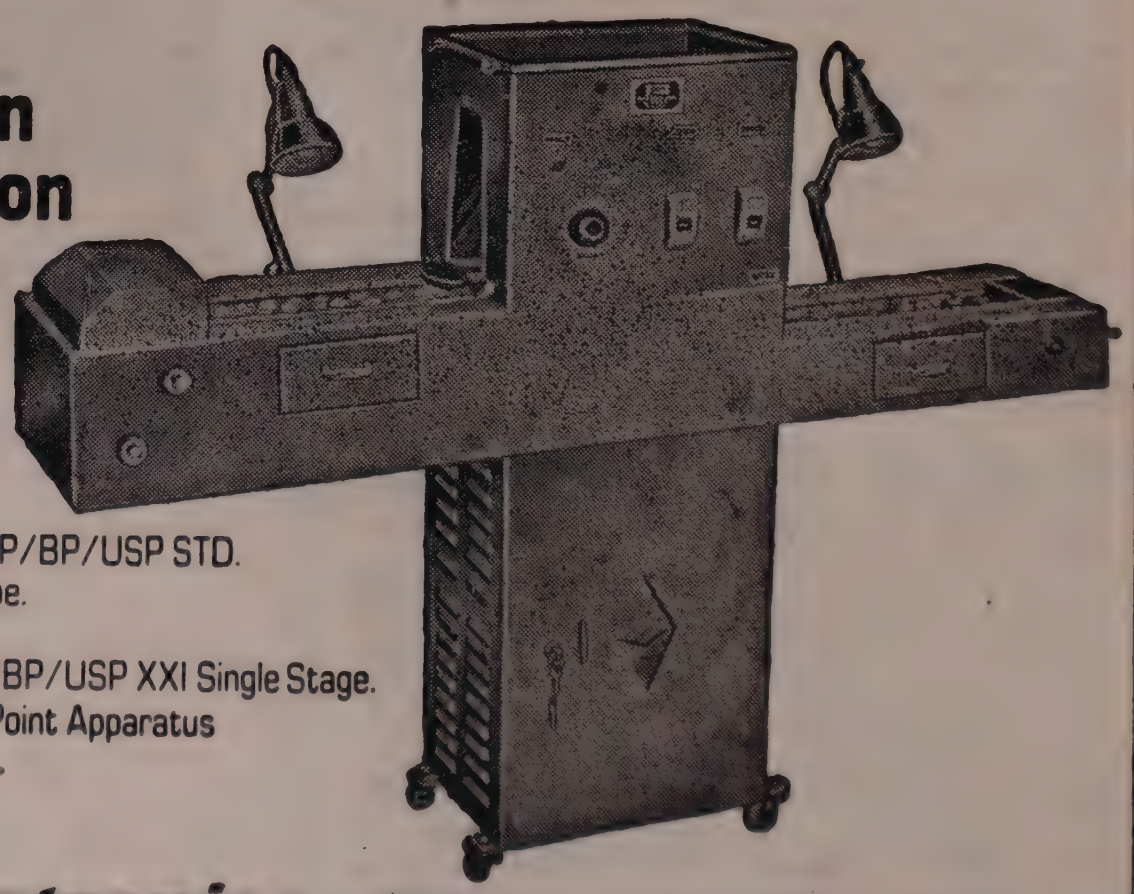

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FOREIGN NEWS

Probucol's Efficacy In Reducing Cholesterol

SAN DIEGO : United States scientists now believe they may have discovered the way in which cholesterol causes the clogging of arteries, leading to most heart attacks, and how certain drugs may now be able to prevent this life-threatening process.

Laboratory studies found that cholesterol, carried in the blood by low density lipoproteins, must undergo oxidation (become rancid) before it can accumulate in blood vessel walls.

Described as the most convincing explanation yet of how cholesterol is trapped in arterial walls, and then changed to produce fatty streaks and plaques causing clogging of arteries, this discovery is an important new lead for Nobel-prize winning heart researchers, Drs Michael Brown and Joseph Goldstein.

Many researchers are now seeking to confirm the findings that cholesterol must be oxidized to initiate plaques, and that plaques can be prevented if oxidation can be blocked.

Testing the oxidation theory in rabbits prone to atherosclerosis, researchers from the University of California in San Diego recently gave a group of rabbits probucol, a drug marketed as a cholesterol-reducig agent.

Probucol is available on prescription in Australia as Lurselle.

After seven months of treatment, the rabbits receiving probucol had a "striking decrease in lesions," said Dr Steinberg from the University.

Congress Of The European Pharmacopoeia

STRASBOURG : Nearly 500 persons from the pharmaceutical professions met at the Council of Europe in Strasbourg for the Congress of the European Pharmacopoeia.

The participants, from the nineteen countries which have signed the convention of the European Pharmacopoeia, as well as from countries such as the United States, Japan, Thailand, and Poland, examined the problems associated with the harmonisation of national legislation on the quality control of medicinal substances.

A viariety of pharmaceutical subjects of current interest such as the replacement of biological methods and the validation of anlytical procedures were dealt with. Much of the discussion was devoted to the role of the European Pharmacopoeia in the future regulatory system for medicinal substances in Europe.

The ministers of health of Portugal and the United Kingdom, Mrs Belleza and Mr Mellor, participated in the work of this congress, which was opened by Mrs Lalumiere, the Secretary General of the Council of Europe. She praised the Pharmacopoeia as the "concrete result of good European co-operation".

Messrs Morris and Martino, members of the Parliamentary Assembly and representatives of the Social, Health, and Family Affairs Committee stressed the role of the European Pharmacopoeia in consumer protection, since it guarantees the quality of medicines, especially generics.

All the participants expressed a desire for effective co-operation with the EEC, in order to develop a cohesive regulatory framework in Europe.

In his general conclusions, Professor Sjoholm noted the advantages of a common language and a harmonised system of standards. All the participants (quality control authorities as well as representatives of industry) underlined the usefulness of the European Pharmacopoeia as a single reference.

Professor Sjoholm then used the example of the Scandinavian countries, which gave up their national pharmacopoeias in 1965 to create a common nordic pharmacopoeia and which in 1975 began to contribute to the work on the European Pharmacopoeia, to demonstrate how efforts should progressively converge in order to elaborate single standards which are able to satisfy national requirements and, of course, the needs of Europeans.

To accomplish this goal, the European Pharmacopoeia will have to establish more and more monographs and general methods for reference use, in an increasing number of areas, whilst meeting tighter and tighter deadlines.

Collagenase Inhibitors Provide Hope For A Radical Cure Of Arthritis

PHILADELPHIA : Research on inhibitors for the human enzyme collagenas in USA, has shown that collagenase inhibitors can provide new drugs against arthritis.

Smith Kline Beckman (Philadelphia) and British Biotcehnology have been collaborating on arthritis research since 1987. Now they are endeavouring to develop and commercialize inhibitors for the human enzyme collagenase, which destroys bone and cartilage in the joints of rheumatoid and oesteoarthritis patieuts. SKB will support clinical trials and will market the drugs worldwide. British Biotechnology will market them in Europe.

Photo-Dynamic Therapy Makes A Debut In Canada

VANCOUVER : Quandra Logic Technologies of Vancouver, Canada has made recently a patent application in USA on a group of light activated drugs (US Pat. application No. 041680). This patent application, according to chief executive officer J. Miller, will secure for the company the position as the world leader in the development of photodynamic therapy.

This new therapy makes use of lasers, fiber optics and light activated drugs in the treatment of cancer, heart disease, sexually transmitted diseases and psoriasis. It can also destroy viruses in the blood. The patent covers derivatives of benzoporphyrin that will be put through toxicology and clinical trials later this year.

A Test Kit For Rapid Diagnosis Of Syphilis

LONDON : Wellcome Diagnostics (UK) has recently launched a new TPHA assay with an incubation time of only 45 mins for the rapid diagnosis of syphilis.

The Wellcosyph HA Kit provides a rapid assay for the detection of antibodies to Treponema pallidum by indirect haemagulation. With random blood donor samples the assay demonstrated 99.75% specificity and using clinical samples showed a specificity of 99.4% and sensitivity of 98.7%

Each kit contains sufficient reagents to perform either 200 screeing tests or 22 quantitiative assays. All reagents are supplied ready-to-use and one stable at 2-8°C removing the need for reconstitution and reducing wastage.

Hoechst And Bayer Test AIDS Drug

LONDON : Hoechst (U.K.) and Bayer (U.K.), have begun testing the anticoagulant dextran sulphate as a possible treatment for AIDS.

They have also secured the rights to sell the drug for the purpose of treating AIDS, should the tests prove successful.

Though no preliminary findings have been released in order "not to awaken false hopes in AIDS patients", similar tests in the United States have shown promising results, reported a recent edition of *The Canadian Pharmaceutical Journal.*

Towards An Insulin Pill

JERUSALEM : The end of the era of the human pincushion may be in sight for the tens of thousands of diabetics who take their daily insulin by injection. A team of researchers at the Hebrew University-Hadassah Medical Center in Jerusalem has recently been granted U.S. and Israeli patents for an insulin pill that has emerged out of a decade of research.

Insulin, the hormone that regulates glucose in the body, is a life-saver for diabetics. But its replacement by daily injections is not enough: introducing insulin in surges rather than keeping it at a constant level can result in a variety of health problems from blindness to cardiovascular disease.

The development of an insulin pull, however, has been held up by two major problems.

New Light On The Physiological Toxicity Of Aluminium

LONDON : Aluminium is effectively excluded from absorption into the human system by the impermeability of the normal gut. When aluminium does penetrate the system, however, it is deleterious. ALS-Parkinsonism-dementra complex of Gnam, renal dialysis dementia and aluminium-induced encephalopathy all exhibit the presence of Al in the brain.

SEM and proton microprobe X-ray techniques can be used as an insoluble alumino silicate core surrounded by a glycoprotein sheath in senile plaques and neurofibrillary tangles.

Al. is also implicated in Down's syndrome and in osteomalacia, a bone-softening disease. Detection of Al at low levels is difficult because of the high background in any environment where analysis must be conducted. The detectable levels of Al in foods has continually declined as techniques have improved, and non electrothermal atomization AA spectrometry is capable of making the necessary determinations.

Oxidation-Resistent Oils For Modern Drug Delivery Systems Developed By Crode

NEW YORK : Chromatographically purified vegetable oils that have low peroxide values have been recently developed by Crode (New York, USA). Oxidized impurities have been removed from the company's super-refined oils to minimize interaction with sensitive lipophilic drugs of vitamins during solubilization.

Fatty acid distribution of the oils is maintained between crude and refined stages. The colorless and odourless oils are available in USP/NF grades and are suitable for use in modern drug-delivery system.

New Volume USPDI 1989 Edition Published

WASHINGTON : In USA, The 1989 edition of USPDI published recently includes a third volume that contains federal and state manufacturing and dispensing requirements. The new volume also include the entire text of the FDA 'Orange Book', Approved Drug Pro-

ducts with Therapeutic Equivalence Evolutions. Abstracts of USP/NF monographs on strength, quality, purity, packaging, labelling and storage are included, as are selected USP/NF General Chapters and General Notices.

The volume also includes FDA GMPs and other federal regulations. Like USPDI Volumes I & II, Volume III is updated bimonthly. The publication is available from USP's Drug Information Division, 12601 Turnbrook Parkway, Rockville, MD 20852, USA.

Rheumatrex (Methotrexate)—A New Drug Against Rheumatoid Arthritis

NEW YORK : Lederle Laboratories has recently received FDA approval for its new drug against rhenmatoid arthritis (RA). The new drug called Rheumatrex (Methotraxate). This new drug produced rapid relief in approximately 70% of the voluntary participants in an eight year study. Methotrexate can show result immediately and great reduction of pain and sweling in 6 to 12 weeks. Most other drugs take up to 6 months to help RA Patients.

Only small group were involved in long term studies of methotrexate, and there were indications that in rare cases, problems including liver damage or bone marrow toxicity can occur. The Company claims this new drug as a new landmark in RA therapy. The drug is now available in the US Market by prescription.

According to the American Arthritis Foundation (New York), approximately over 2.11 million in USA are affected by RA and three-fourth that are women.

New Contrast Media From MallinKrodt & Molecular Biosystems

ST. LOUIS : Mallinkrodt (St. Louis, Mo, USA) has gained FDA's approval for Optiray (loversoil) a non-ionic contrast medium for radiology and cardiology X-ray procedures. The Company notes that the product is the only one developed in ISA that has been approved by FDA in recent years. The market for X-ray contrast media is currently $ 500 million in USA alone and may hit $ 1 billion in 1993. The world market is twice that size.

In addition, Molecular Biosystems Inc. (San Diego, CA) has agreed to give Mallin Krodt exclusive North and South American marketing and distribution rights for Albunex, an ultrasound imagery and contrast agent. Mallinkrodts scales of contrast media are expected to grow at a coupoundrate of nearly 20% during the next few years.

Rub-In Aspirin Formulation Developed In Australia

ADELAIDE : An Australian pharmacist has developed a rub in aspirin formulation, which is expected to enter world market in 1989. The product will be marketed by the Adelaide company, Deltona pty.

Ian Tindall's cream is claimed to be in advance of other creams which allow drugs to pass into the bloodstream through the skin. Alcohol based creams have been used in the past end, while reasonably effective, they do not get through the skin quickly.

World's Top Leading Pharmaceutical Products

NEW YORK : The World's leading 15 pharmaceutical products (ranked by estimated 1987 sales in $ million) are listed below :

Rank	Brand	Company	Therapeutic Class	Sales in $ million
1.	Zentac	Glaxo/Sankyo	H -antagonist	1479.00
2.	Tagamet	Smith Kline	H -antagonist	1132.00
3.	Tenormin	ICI	Beta blocker	867.00
4.	Capoten	Squibb	ACE—inhibitor	779.00
5.	Vasotec	Merck & Co	ACE—inhibitor	635.00
6.	Adalat	Bayer/Takeda	Ca—antagonist	587.00
7.	Naprosyn	Syntex	NSAI	555.7
8.	Voltaren	Ciba-Geigy	NSAI	544.1
9.	Feldene	Pfizer	NSAI	523.8
10.	Ceclor	Eli Lilly	Oral antagonist	515
11.	Cardizem	Marion	Ca-antagonist	425
12.	Zaditen	Sandoz/Sankyo	Anti-eathmatic	398
13.	Ventolin	Glaxo	Broncho-dilator	387.7
14.	Inderal	ICI/AHP	Beta blocker	376.2
15.	Amoxil	Beechem	Antibiotic	368.5

Transdemal Estrogen Replacement Therapy On The Horizon

MIAMI : Researchers at Noven Pharmaceuticals (Miami) are pursuing through research a $ 100 million/yr market by early 1990s transdermal estrogen replacement. The Company recently completed tests showing its estrogen patch delivers a steady does and does not irritate the skin even after 96 hours. Testing will continue in preparation for filing with the FDA.

According to Noven researchers, estrogen replacement prevents hot flashes, insomina and osteoporosis in post-menopausal women, who lose most of their ability to produce the hormone.

An Improved Allergy Test System Unveiled By Pharmacia (Sweden)

COPENHAGEN : A new automated system for allergy testing called Pharmacia Cap System has been introduced in Sweden. Clinical studies performed with the new system on approximately 7000 patients in six countires show that up to another 15% allergy sufferers can be detected.

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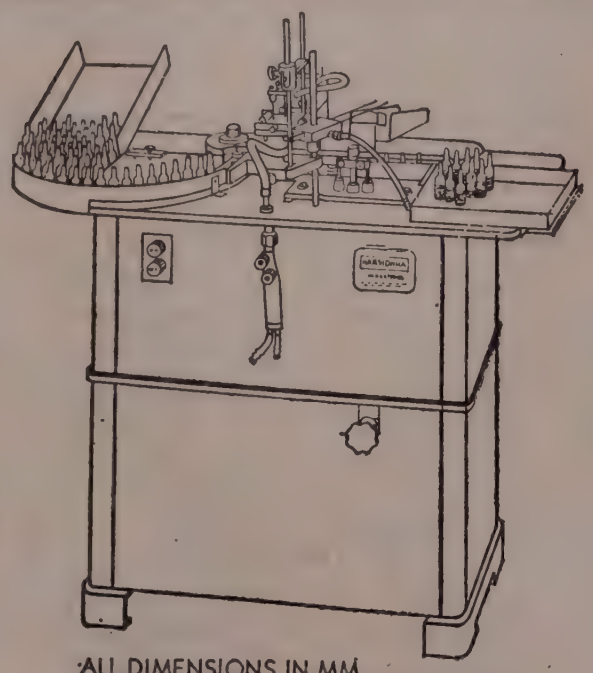
VERTICAL VERY COMPACT UNIQUE AUTOMATIC SINGLE HEAD AMPOULE FILLING & SEALING MACHINE MODEL-HFS-60

EVEN, VIALS FROM 2 ML TO 25 ML UPTO A MAXIMUM OF 25.4 MM DIA CAN BE CONVENIENTELY FILLED.



ALL DIMENSIONS IN MM
840 MM (L) x 460 MM (W) x 1065 MM (H)

OUT PUT 45 AMPOULES OR VIALS/MINUTE

SALIENT FEATURES :

- TOTAL VERTICAL MOVEMENT AND WHILE FILLING CENTERING BOTH FROM BOTTOM & TOP. ANGULAR PRE-HEATING & SEALING BURNER'S, ENSURES 'NO CHARRING' AT TIPS & UNIFORM SEALING OF AMPOULES AVOIDING COSTLY REJECTION.
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- VARIABLE SPEED PULLY DRIVE ALLOWS GREATER FLEXIBILITY & TOLERANCES ON AMPOULE NECK DIAMETER.
- NO RE-ARRANGEMENT REQUIRED FOR NEXT OPERATION, AS AMPOULES ARE COLLECTED IN THE TRAY IN VERTICAL POSITION.

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With the automated system, lab staff will save approximately 30% of hands-on-time. The Pharmacia Cap System also increase the reliability of the follow-up patients. The allergen is bound to a carrier with a porous three dimensional structure encolosed in a plastic capsule, instead of being bound to small paper discs. More allergies can be bound in this way, which enhances the discs. More allerfies can be bound in this way, which enhances the sensitivity and precision of the test.

The new system is a further development of the Phadebas Rast, a test that has been on the market for 15 years and is one of the company's best selling products, reports the manufacturers, Pharmacis Diagnostics of the Swedish Pharmacia group.

Novel Contraceptive Based On Flexible Plastic Ring From Organon

LONDON: A new type of contraceptive which provides several advantages over the contraceptive pill is undergoing trials in 10 countries in Europe. The contraceptive device is a small flexible plastic ring which releases tiny amounts of two of the hormones that are normally contained in the oral contraceptive pill.

The woman inserts the ring into the vagina, where it stays, held in place by the vaginal muscles. The woman removes the ring for one week in very four in the same way as women on the pill stop taking tablets. During the week bleeding resembling a period takes place.

The current trials aim to assess the acceptability of the vaginal ring. According to Organon (Holland), more than 90% of women who have used the ring said that they preferred it to other methods of contraception.

One obvious advantage of the vaginal ring is that the woman does no have to remember to swallow a tablet every day. The addition the ring has two other salient advantages which make it safer than the pill:

(i) First because, a woman takes the pill only once a day, absorbing the hormones through the gut, blood levels of the hormones vary over a wide range. In contrast, the body absorbs hormones, from the ring at a steady rate through the Vaginal wall.

(ii) The second and possibly most important advantage is the ring's limited impact on the liver. Hormones asorbed through the gut pass directly to the liver, which is loaded with the brunt of relatively high dose. In contrast, hormones released from the ring to directly into the bloodstream and bypass the liver.

Researchers believe that high level of sex hormones entering the liver are responsible for the major side-effects of the pill. The ring will minimize the side effects of the pill and therefore will be more acceptable. The device has reached clinical trials because of a breakthrough in design. Tests on an earlier vaginal ring began

in 1971. But the stiff, inflexible design of the early rings was unacceptable. The new ring is wrapped in a soft silastic membrance which is easier to insert and more comfortable to wear. The rate limiting membrance, which gradually seep out the hormones in the ring, plays a significant role.

Further extensive trials in Britain are planned. However, it may be another five years before the ring will be available in the market.

74th Session of the European Pharmacopoeia Commission

STRASBOURG : Ms Agnes Artiges was elected Chairman of the European Pharmacopoeia Commission.

Ms Artiges had been a long-standing member of the French delegation and she had participated in the work of the Commission since the first edition in 1976.

She is currently the vice-director of pharmaceutical affairs in the Department of Health in France.

Ms Artiges is an expert of the French delegation to the Committee on Proprietary Medicinal Products and to the Committee on Proprietary Veterinary Products, and also of its EEC working parties.

Her three-years mandate as Chairman of the Commission begins at the Autumn session in November 1989.

By virtue of her election, Ms Artiges is no longer a member of the French delegation, in accordance with Article 2 of the Convention.

Siberian Herbs To Cure Cancer

MOSCOW : Many years of clinical practice with traditional herbal preparations in combination with modern methods of treatment has yielded promising results in curing many diseases, considered incurable, including chronic lever troubles and the killer disese of the century-cancer.

This method has been found particularly successful by Siberian medics. For example, psoriasis, a skin disease which normally very seldom responds to treatment, has been found curable with local herbal medicine which give complete cure to 65 per cent patients treated. Though the period of treatment is quite long, ranging from six months to two years, the herbal preparation has no hormonal effects and the patient needs no hospitalisation. The plant from which the medicine is extracted grows only in the unique climatic conditions of Siberia, and that too only in a small part of the vast land.

Another drug derived by Siberian scientists from the common plant called saltwort has been found to have wonderful restorative effect on damaged livers. Tentati-

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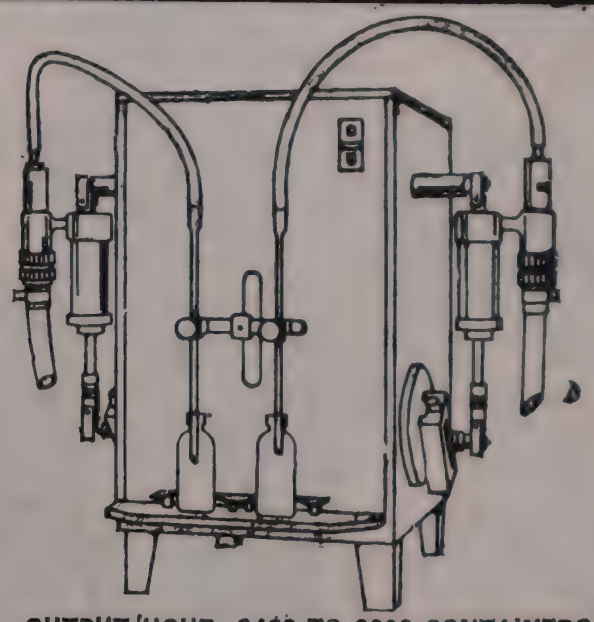
MODEL SLF-50



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- ACCURATELY DESIGNED & MANUFACTURED NON RETURN VALVE FOR DRIP PROOF PERFOMANCE TO AVOID MESSY PLATFORM & CONTAINERS.
- QUICK CHANGE OVER OF SYRINGES, DISMANTLING FOR MAINTENANCE & CLEANING POSSIBLE WITHOUT ANY HINDERANCE.

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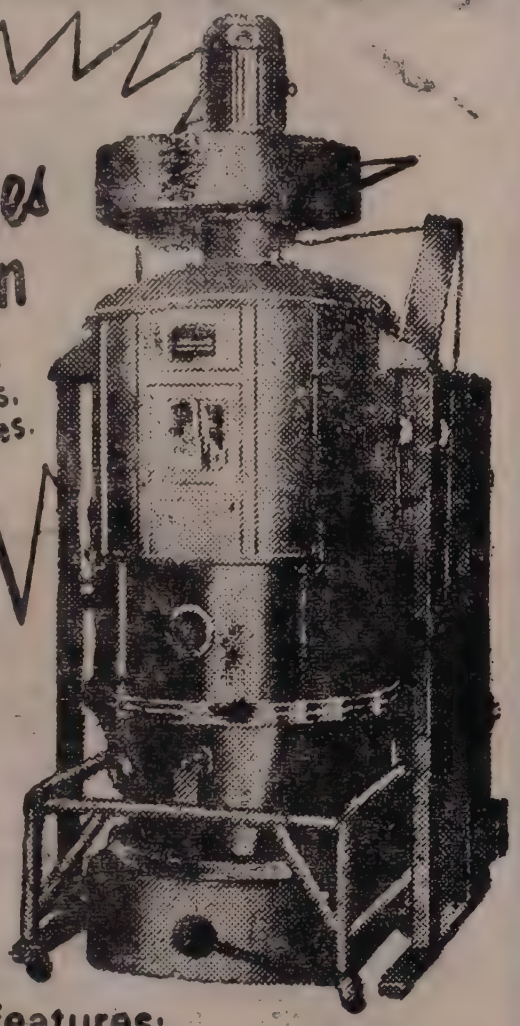

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tively named Salsocollin, the medicine is considerably cheaper and has not side-effects.

Of great significance is a new drug developed by Siberian scientists on the basis of a locally available medicinal plant for the treatment of cancer. It is developed on the basis of diamond-to-cut-diamond-method. Experiments with extracts derived from tumorous tissues of a locally grown plant on animals with malignant tumours showed promising results. When the medicine was adminsitered on cancer patients, considered hopeless, the results were encouraging.

The Siberian scientists have gatheed enough scientific experimental data which indicate that a certain group of patients with the fourth phase of cancer (up to 20 per cent) can be saved by the new drug. It is known that traditional medicine is helpless in treating patients in the fourth phase of cancer. The preparation acts as an immuno stimulator and restores the activity of the human immune system when it breaks down for reasons which are still to be ascertained and fails to fight cancer cells.

The new preparation is still under development and requires further clinical studies. Research on this medicine is continuing. Some of the researchers are of the view that this drug may prove effective against AIDS too. This is because it stimulates the growth of T-lymphocytes which get quite scarce in the case of AIDS patients.

Meanwhile, to speed up the development of the drug, the Siberian scientists are prepared to go in for joint ventures with foreign firms on a mutually beneficial basis.

Safety Of Self-Donated Blood For Surgery

WASHINGTON : An alternative to use of the public blood supply currently available is donation of one's own blood—autologous blood—before a scheduled surgery for one's personal use during the surgery. Such a procedure is based on the medical fact that receiving one's own blood during and after surgery is better and safer than receiving someone else's blood.

Donating one's own blood for future use has definite advantages, such as eliminating the risk of transfusion reaction and of hepatitis, more rapid replacement of body blood during surgery, since production of blood cells in the bone marrow has already been trigerred by the removal of blood during donation; and less demand on the community's blood supply.

A person can safely give one unit of blood per week for up to 6 weeks, depending on the anticipated need. Blood is then labeled for that patient's use only and is kept ready at the hospital for the operation. A final donation can be made no less than 3 hours before the scheduled surgery, which allows time for the body to replenish its fluid volume.

The National Institute of Health endorses the use of autorogous blood for scheduled, elective surgery, but

does not endorse long term storage or stockpiling with no imminent need because of certain limitations.

Transgenic Plants Harnessed For Production Of Pharmaceuticals Peptides

GHENT (Belgium): Plant Genetics System (PGS) of Ghent, Belgium, has developed a method for transferring human genes into plants, which has the potential to be used for the production of pharmaceuticals. The peptides made by the plants are stored in specific organs, such as seeds, and can be extracted by a simple process.

The technology was developed by PGS in collaboration with Dr. J. Vandekerckhove at the University of Ghent. It involves replacing part of the gene for a plant's storage protein with the gene for the required enkephaline, have already been produced in plants (Arabidopsis thaliena, phale cress) using the new technique, and peptides with up to 50 amino acids could probably be produced according to Dr. Vandekerckhove. The enkephalins were pharmacologically active, and although it is not known yet whether larger, more complex peptides are produced in their native active form, the extraction processes used for the plant produced peptides are less disruptive than those used in other forms of manufacture. Greenhouse experiments have confirmed that peptides can be produced in very large quantities in the seeds of oilseeds rape. PGS plans to engineer the transgenic plants and extract the product, and then sell it to a pharmaceutical company for further processing. The first agreement with an unnamed pharmaceutical company has already been established.

PGS was founded in 1983 and has genetically engineered insect, virus and herbicide resistant plants. It has also engineered blue-green algae to produce proteins that kill mosquito larvae.

Radiation And Cancer

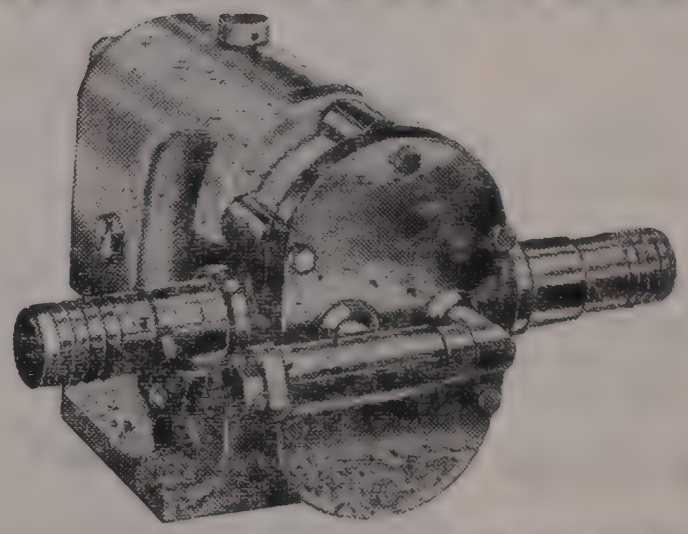
LONDON : Scientists in Britain are to investigate the possible existence of a so far undiscovered link between low levels of radioactivity in the environment and the incidence of childhood leukaemia.

A five-year £3 million research programme funded by the UK nuclear industry will co-ordinate projects in laboratory-based experimental radiobiology, which might reveal evidence of a biological mechanism linking low-level ionising radiation and cancer, along with a series of epidemiological studies into the distribution of leukaemia and other cancers in the population.

The research is being supported by the UK Atomic Energy Authority, British Nuclear Fuels, which is a world leader in nuclear fuel services, and the Central Electricity Generating Board which operates 10 nuclear power stations around Britain.

It is planned to include national study of childhood leukaemia, a health study of workers at nuclear installations linked to international surveys of the same type, and investigation of the effect of radon, a naturally-occurring

? ! ? WHY A LOBE PUMP THAT NEEDS NO INTRODUCTION...



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'GOMTEERA'

radioactive gas produced by granite rock in the earth, which is the main cause of exposure to low-level radiation in Britain.

Researchers will also use the latest molecular biology techniques to study the genetic and environmental causes of cancer and the role of radiation in inducing the disease. They will aim at developing techniques for screening-out people with genetic abnormalities which could make them particularly sensitive to the effects of nuclear radiation.

The programme will also explore the evidence for a virus or infection being the cause of leukaemia.

It will be under the control of the UK Co-ordinating Committee on Cancer Research, an independent national body which represents the major national cancer research charities and Britain's Medical Research Council.

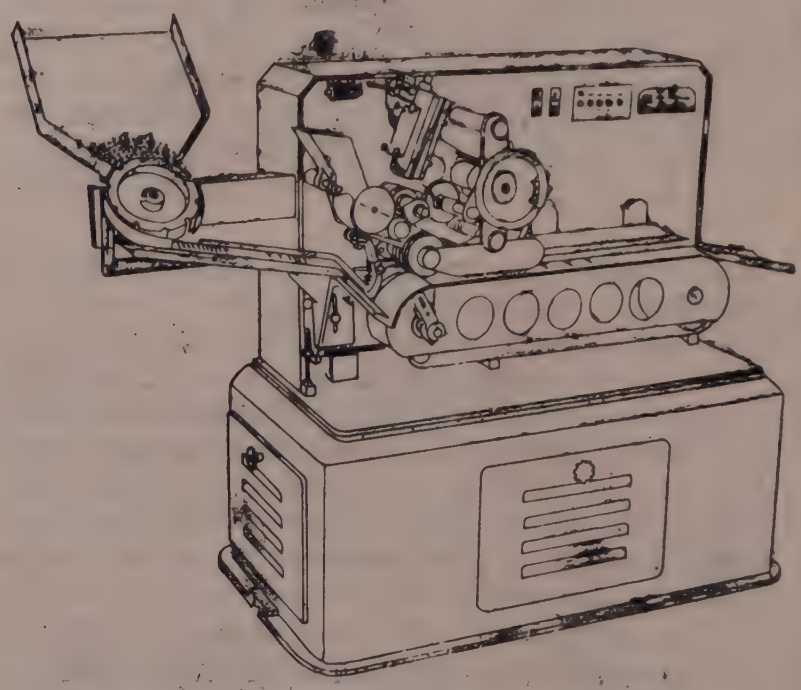
Top 15 Pharma Markets In The World

LONDON : 15 countries accounted for 86.4% of the worldwide pharmaceutical market (excluding Eastern Bloc Countries) 1987, according to the estimates of IMS, U.K. The share of U.S. was 28.3% followed by Japan (21.6%), Federal Republic of Germany (9.0%), France (6.4%) and Italy (6.0%) India, with a percentage share of 1.6%, was ahead of Brazil, Mexico, South Korea and Argentina among the developing countries. The following table gives the ranking of the top 15 countries:—

15 Largest Pharmaceutical markets in the world—1987 excluding Eastern Bloc Countries)

	(Million U$)	%
United States	33,223	28.3
Japan	25,359	21.6
Federal Republic of Germany	10,558	9.0
France	7,559	6.4
Italy	7,031	6.1
United Kingdom	3,699	3.1
Canada	2,435	2.1
Spain	2,415	2.1
India	1,822	1.6
Brazil	1,684	1.4
Mexico	1,315	1.1
South Korea	1,206	1,0
Argentina	1,200	1.0
Belgium	1,081	0.9
Netherlands	984	0.8

AMBA



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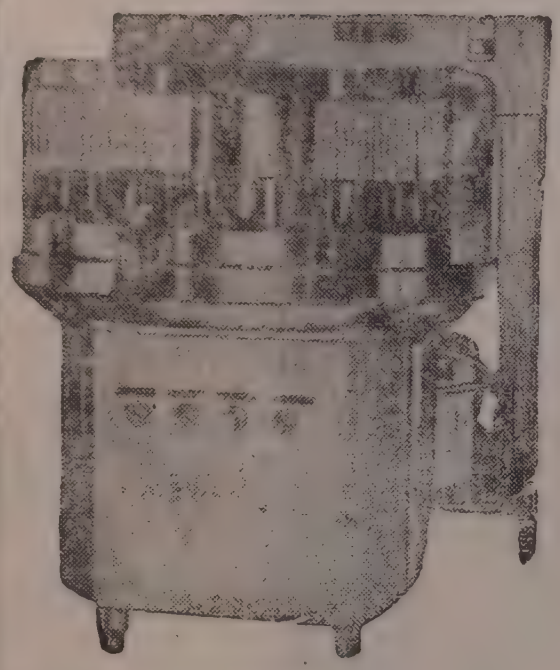

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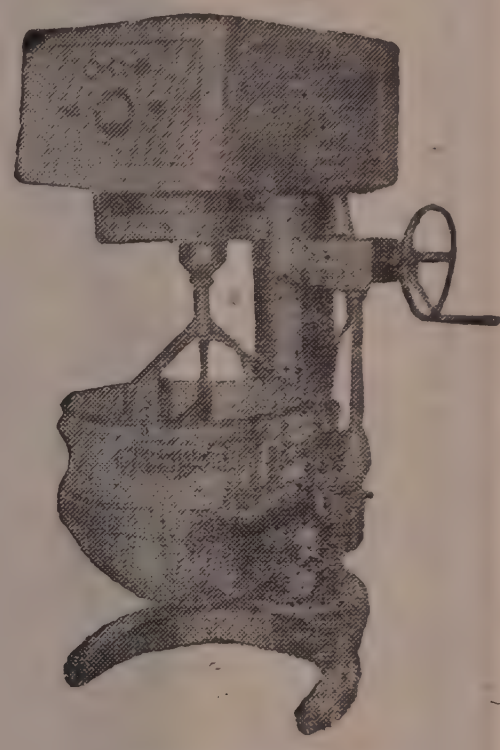
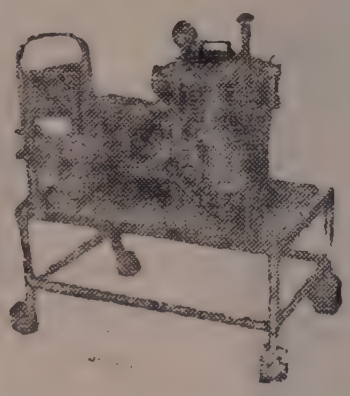


Planetary Mixer



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	iv)	D-Para Hydroxy Phenyl Glycine Dane Salt (Methyl Pot)
	v)	D-Para Hydroxy Phenyl Glycine Base
AMPICILLIN TRIHYDRATE	i)	Penicillin G Potassium First Crystals
	ii)	Penicillin V Potassium First Crystals
	iii)	6 APA
	iv)	D-Alpha Phenyl Glycine Chloride Hcl/Base
CEPHADROXIL		D-Para Hydroxy Phenyl Glycine Chloride Hcl
CEPHALEXIN		7 ADCA
CEPHALORIDINE / CEPHAZOLINE		7 ACA
CEPHRADINE		D-Alfa Dihydroxyphenyl Glycine
CHLORAMPHENICOL	i)	L Base
	ii)	Schiff Base
CIMETIDINE	i)	Cyano Dimethyl Di Thio Carbamate
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	iii)	5 Methyl 4 Hydroxy Methyl Imidazole
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CLOXACILLIN SODIUM		(Chloro-2-Phenyl) 3-Methyl-5 Isozazolyl Carbonyl Chloride (CIMC CL)
DIPYRIDAMOL	i)	5 Aminocrtic Acid
	ii)	2-6 Dichloro-4-8 Dipiperidino Pyrimido (54-D) Pyrimidine
ERYTHROMYCIN STEARATE/ESTOLATE		Erythromycin Thio Cyanate
ISONIAZID	i)	4 Cyanopyridine
	ii)	Gamma Picoline
MEBENDAZOLE	i)	P-Chloro Benzoic Acid
	ii)	4 Amino 3 Nitro Benzo Phenone
	iii)	3.4 Diamino Benzophenone
NIACINAMIDE	i)	3 Cyanopyridine
	ii)	Beta Picoline
NORFLOXACIN	i)	3 Chloro 4 Fluoro Aniline
	ii)	7-Chloro 6-Fluoro 1,4 Dihydro 4 Oxo 3 Carbethoxyquinoline (Cyclizate)
	iii)	7 Chloro 6-Fluoro 1 Ethyl 1,4 Dihydro 4 Oxo 3 Carboxy Quinoline
RANITIDINE	i)	Furane 2 Hydroxy Methyl 5 Dimethyl Amino Methyl
	ii)	N-Methyl-1 Methylthio-2 Nitro Ethenamine
	iii)	1,1 Bismethyl Thio-2 Nitro Ethene
	iv)	Dimethyl Amine Hcl
RIFAMPICIN	i)	3 Formyl Rifamycin SV
	ii)	Rifamycin S
	iii)	Rifamycin S Sodium
TRIMETHOPRIM	i)	3-4-5 Trimethoxy Benzaldehyde
	ii)	3-4-5 Trimethoxy Benzoic Acid
	iii)	Gallic Acid
VERAPAMIL HCL	i)	1 Brom 3 Chlorpropane
	ii)	Homoveratrylamine

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TRADE NOTES AND NEWS

New Products & Packings :

M/s. Ranbaxy Laboratories Ltd., New Delhi-110 019.

REVITAL
CIFRAN } —New Introductions.

Ranbaxy Laboratories have announced the introduction of the complete mind and body revitalizer under the brand name of *Revital* in the form of soft gelatine capsules. The preparation contains balanced formula with vitamins, minerals and lipotropic factors enriched with Ginseng.

The packings and prices of the new preparation are:

	Retailer's Price	*Retail Price*
Revital Capsules:		
Blister pack strip of 10 Caps.	Rs. 29.46	Rs. 34.30

Another new product introduced by Ranbaxy recently is *Cifran* brand of Ciprofloxacin in the form of tablets and infusion. *Cifran* is the most powerful antibacterial which exerts its bactericidal action not only on the rapidly multiplying bacteria but also on slowly multiplying and hibernating bacteria.

The packings and prices of the new preparation introduced are:

	Retailer's Price	*Retail Price*
Cifran Tablets:		
Strip of 5 tabs. × 250 mg.	Rs. 35.40	Rs. 43.00
Strip of 4 tabs. × 500 mg.	Rs. 59.30	Rs. 72.00
Cifran Infusion:		
Bottle of 50 ml.	Rs. 41.18	Rs. 50.00
Bottle of 100 ml.	Rs. 70.01	Rs. 85.00

M/s. Stancare—Division Ranbaxy Laboratories, New Delhi-110 019.

KEFLOXIN—New Introduction.

Stancare have announced the introduction of *Kefloxin* in the form of capsules, tablets and suspension. The preparation is a new advancement in oral cephalosporin therapy. *Kefloxin* contains cefadroxil which effectively covers all gram-positive and virtually all gram-negative organisms, specifically the pathogens most commonly encountered in clinical practice.

The packings and prices of the new preparation introduced are :

	Retailer's Price	*Retail Price*
Kefloxin Capsules:		
Strip of 6 caps. × 500 mg.	Rs. 47.93	Rs. 58.20
Kefloxin Tablets:		
Strip of 4 tabs. × 1 gm.	Rs. 63.91	Rs. 77.60
Kefloxin Dry Powder for Suspension:		
Bottle of 40 ml.	Rs. 17.71	Rs. 21.50

M/s. Glindia Limited., Bombay-400 018.

FORTUM—New Introduction.

Fortum brand of Ceftazidime, a parenteral antibiotic for the treatment of serious infections has been launched in the Indian market recently by Glindia.

Fortum is available in 250 mg., 500 mg., and 1 gm. vials. It is Glaxo Group's latest discovery in the field of parenteral antibiotics and is the first broad spectrum cephalosporin with full anti-pseudomonal activity. It has been particularly found to be effective in the treatment of serious infections including life threatening infections in hospitalised patients.

M/s. Sarabhai Chemicals, Vadodara-390 007.

TRESMOX- New Introduction.

Sarabhai Chemicals have introduced a new preparation in the market containing Amoxycillin Trihydrate and Cloxacillin Sodium under the brand name of *Tresmox* in the form of capsules. Each capsule contains Amoxycillin Trihydrate IP equivalent to Amoxy-

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cillin 250 mg., and Cloxacillin Sodium IP equivalent to Cloxacillin 250 mg.

The packings and prices of the New preparation introduced are :

	Retailer's Price	*Retail Price*
Tresmox Capsules:		
Strip of 6 caps.	Rs. 19.77	Rs. 23.02
Box of 10×6 caps.	Rs.197.70	Rs. 230.20

Bonus Offers & Deals:

M/s. Parke-Davis (India) Ltd., Bombay-400 072.

VANPAR-P—Seasonal Offer.

Parke-Davis have announced an additional discount of 10% on their Product *Vanpar-P* tablets and *Vannar-P* Suspension. The tablets are available in strips of 2's and suspension is available in bottle packs of 8 ml.

The trade will be entitled for additional discount on the products provided they purchase a minimum quantity of 40 strips (tablets) and 20 bottles (suspension) at a time.

The offer is valid from 1st June onwards.

AMPARK-Seasonal Offer.

Parke-Davis have also announced a seasonal offer of 7% additional discount on each purchase of *Ampark* Capsules 250 mg. 10 strips of 10's and/or *Ampark* Capsules 500 mg., 10 strips of 8's and/or *Ampark* Dry Syrup 40 ml. 10 bottles of 40 ml.

The offer is valid from 1st July to 14th September, 1989.

Price Revisions :

M/s. Alembic Chemical Works Co., Ltd., Vadodara-390 003.

PRODUCTS—Prices Revised.

Alembic have announced the revision of prices of the following products with immediate effect :

	Retailer's Price	*Retail Price*
Algesion-O Tablets:		
Strips of 10 tabs.	Rs. 4.33	Rs. 5.04
Althrocin Granules:		
Bottle of 10 ml.	Rs.11.12	Rs. 13.03
Althrocin Liquid:		
Bottle of 60 ml.	Rs. 16.67	Rs.19.54
Althrocin Tablets 100 mg.		
Strip of 10 tabs.	Rs. 10.02	Rs. 11.74
Althrocin Kid Tab. 125 mg.		
Strip of 10 tabs.	Rs. 11.73	Rs.13.75
Althrocin Tablets 250 mg.		
Strip of 10 tabs.	Rs.22.55	Rs. 26.43
Althrocin Tablets 500 mg.		
Strip of 10 tabs.	Rs. 44.44	Rs. 52.09
Pyremol Tablets:		
Strip of 10 tabs.	Rs. 1.94	Rs. 2.27
Pyremol Oral Suspension:		
Bottle of 60 ml.	Rs. 4.18	Rs. 4.90

M/s. Megacare- A Division of Alembic Chemical Works Co. Ltd., Baroda-390 003.

ALZIDE
RIFAMINAL } —Prices Revised.

Megacare, division of Alembic, have announced the following revision of prices of *Alzide* and *Rifaminal* with immediate effect:

	Retailer's Price	*Retail Price*
Alzide Tablets:		
Strip of 10 tabs. × 750 mg.	Rs. 16.56	Rs. 19.72
Strip of 10 tabs. × 1000 mg.	Rs. 22.29	Rs. 27.37
Rifaminal Capsules:		
150 mg. × Strip of 4 caps.	Rs. 3.51	Rs. 4.18
Bottle of 100 caps.	Rs. 85.21	Rs. 101.44
300 mg. × Strip of 4 caps.	Rs. 6.38	Rs. 7.59
Bottle of 100 caps.	Rs.156.80	Rs. 186.67
450 mg. × Strip of 3 caps.	Rs. 7.07	Rs. 8.42
Bottle of 100 caps.	Rs.202.26	Rs. 240.78

M/s. Sarabhai Chemicals, Vadodare-390 007.

SITICOX
MYCOSTATIN } Prices Revised.

Sarabhai Chemicals have announced the price revision of their following products :

	Retailer's Price	*Retail Price*
Siticox Capsules:		
Strip of 3 caps.	Rs. 7.07	Rs. 8.42
Box of 10 × 3 caps.	Rs.70.70	Rs.84.20
Mycostatin Tablets:		
Strip of 10 tabs.	Rs. 17.06	Rs.20.71
Box of 5 × 10 tabs.	Rs. 85.30	Rs.103.55
Mycostatin Vaginal Tablets:		
Strip of 10 tabs.	Rs. 7.95	Rs.9.65
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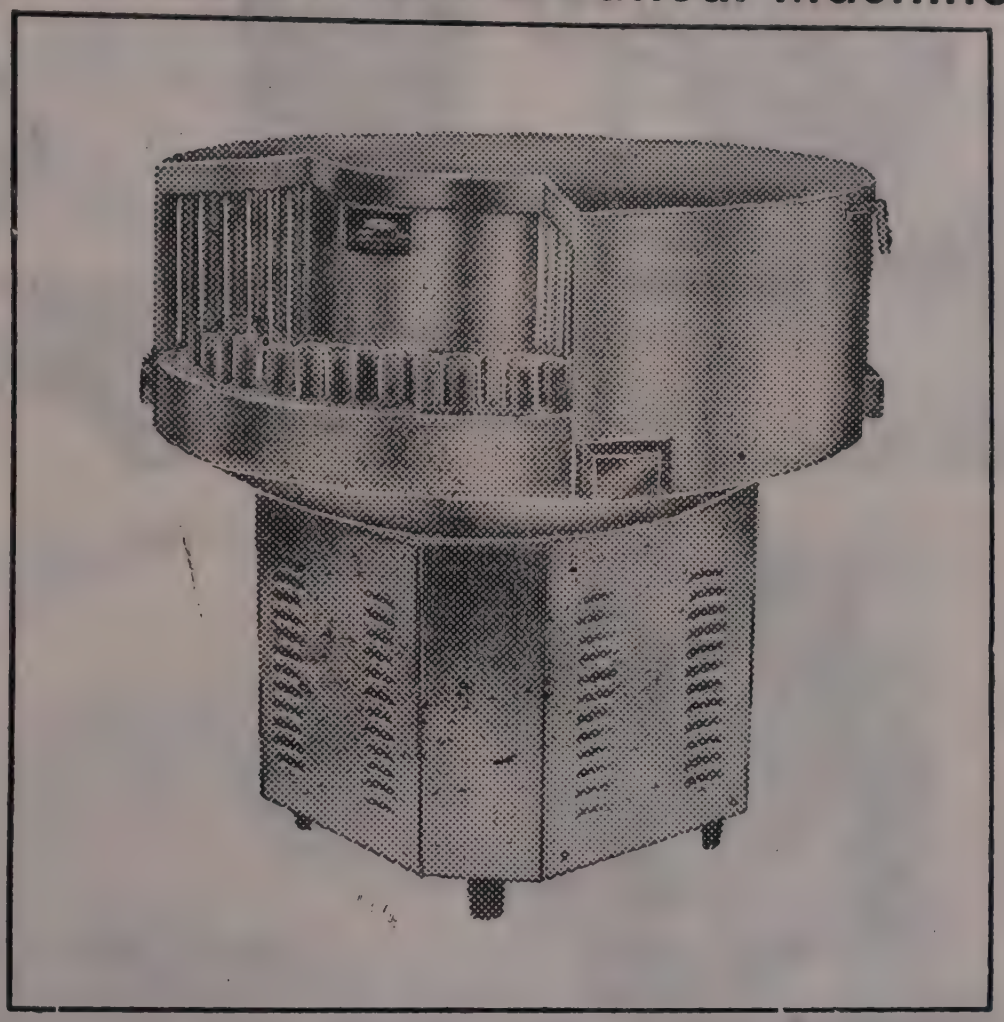

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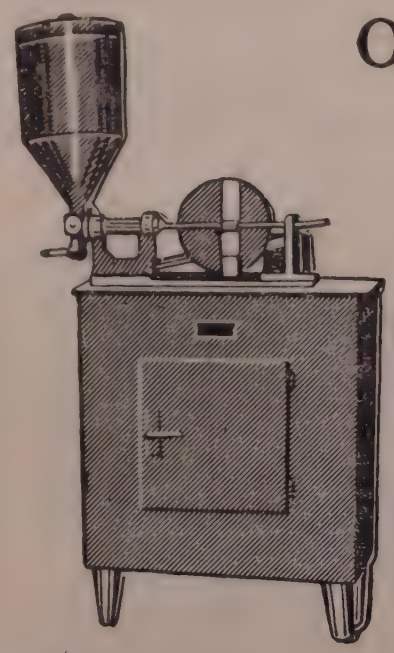
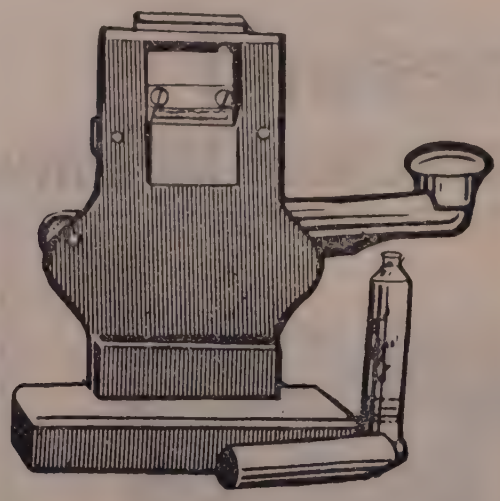
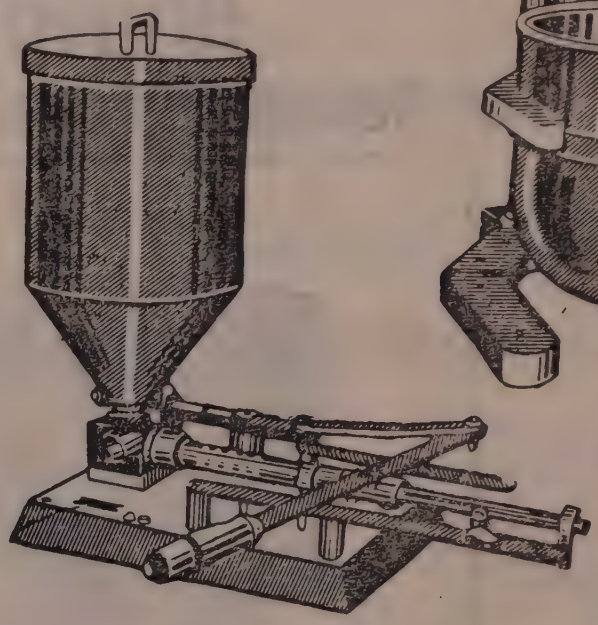
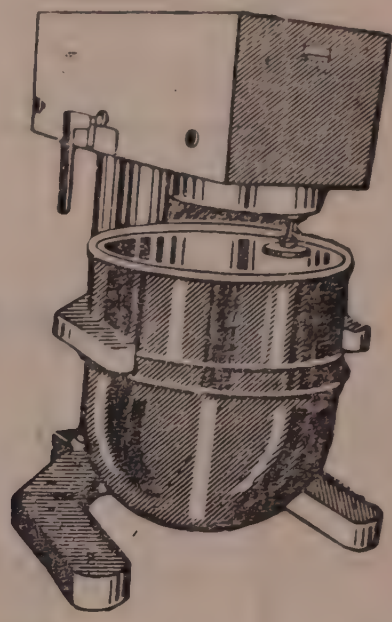


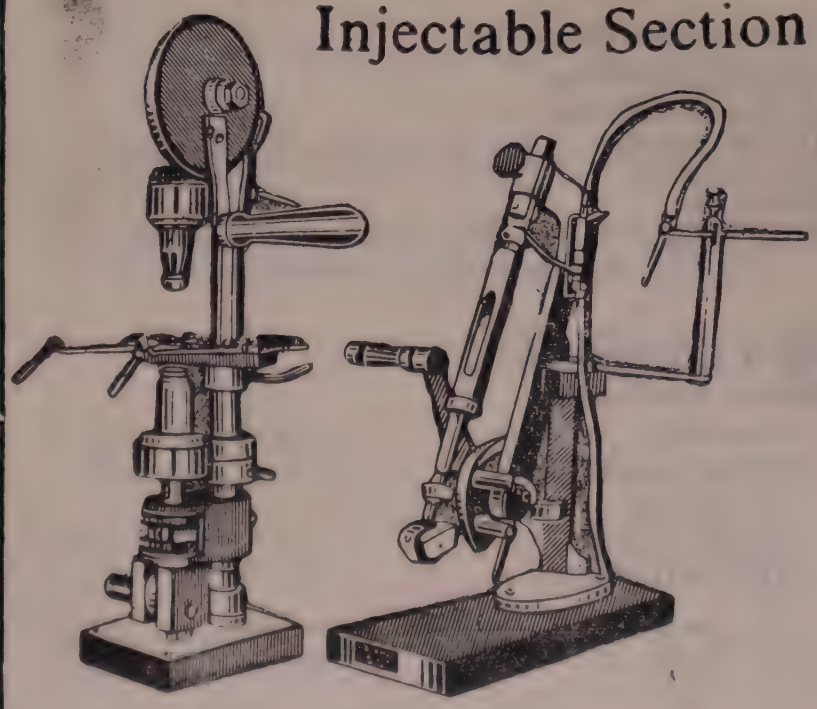






Capsule Section

Injectable Section



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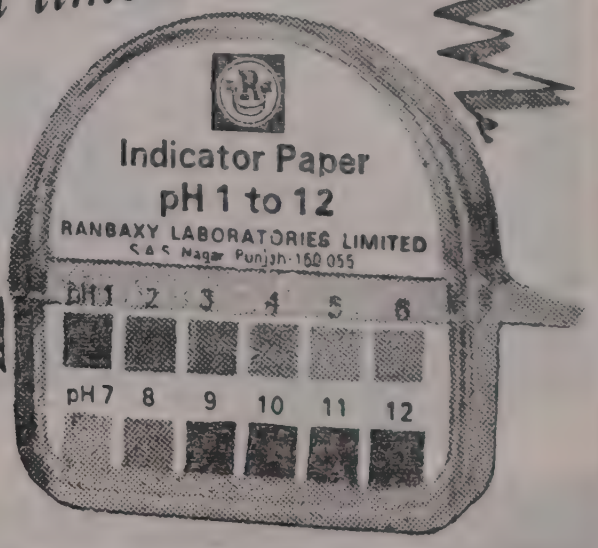

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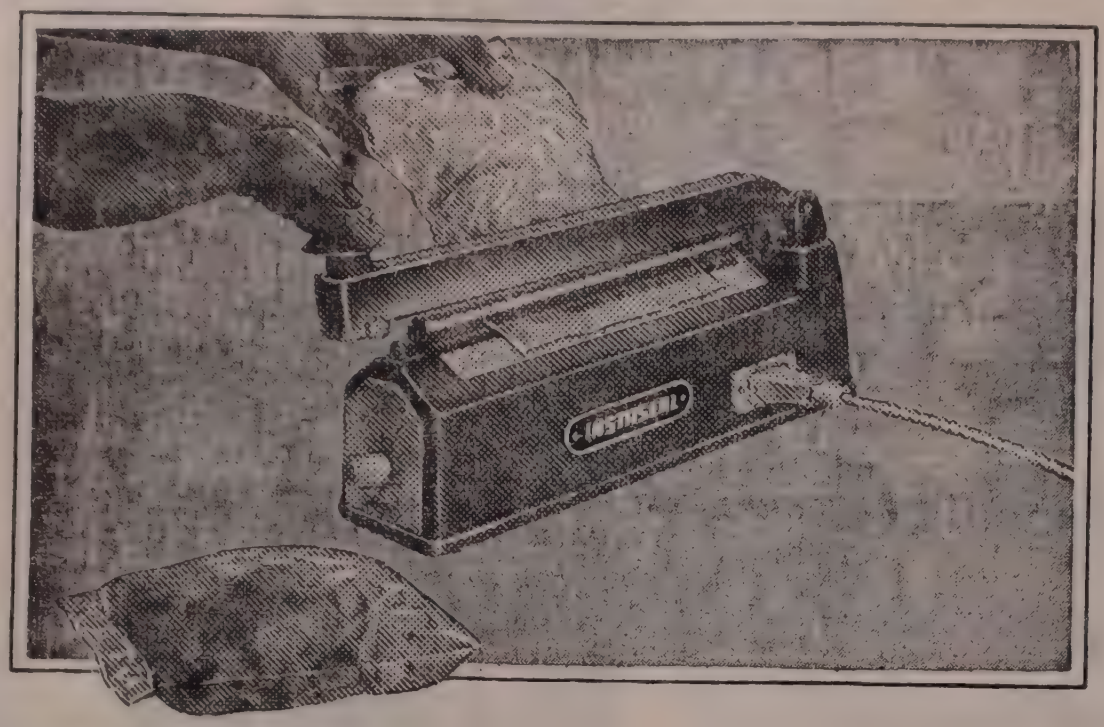

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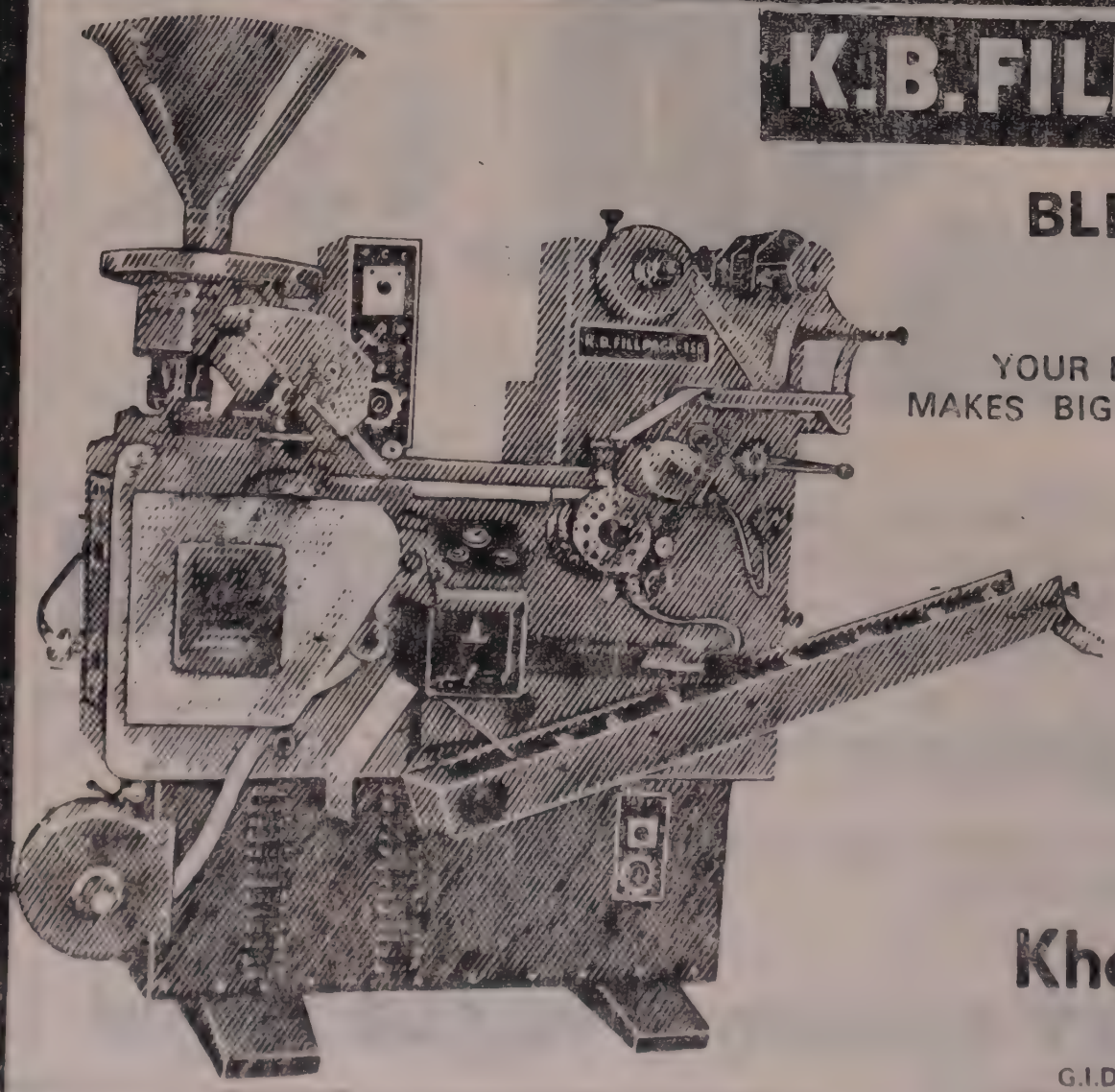

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Scientific Section

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Correspondence and manuscripts should be addressed to The Editor, Scientific Section, The Eastern Pharmacist, 507, Ashok Bhawan, 93, Nehru Place, New Delhi-110019.

SPECTROPHOTOMETRIC DETERMINATION OF SULPHADOXINE AND SULPHALENE IN PHARMACEUTICAL DOSAGE FORMS

G. Ramana Rao*, S.S.N. Murty and I.R.K. Raju
Quality Control Laboratories, I.D.P.L., Hyderabad-500 037.

Abstract

Spectrophotometric methods of estimation of Sulphadoxine and Sulphalene at 485 nm, based on reaction with 1,2-napthaquinone-4-sulphonic acid,sodium salt to form a stable, purple coloured chromogen were reported. The methods obey Beer's law in the range 10-50 mcg/ml.

Introduction

Sulphadoxine [N'-(5,6-dimethoxy-4-pyrimidinyl) sulphanilamide] is official in Indian Pharmacopoeia[1], British Pharmacopoeia[2] and United States Pharmacopoeia[3], while sulphalene [N'-(2-methoxy-3-pyrazinyl) sulphanilamide] is official in Indian Pharmacopoeia-, Sulphadoxine (SD) with pyrimethamine (PM) is official in USP[3] and is used for the prevention, treatment of malaria and is preferred in chloroquine resistant cases. Sulphalene (SP) with pyrimethamine is used in prophylaxis and therapy of malaria. Sulphalene (SP) with trimethoprim (TM) has a broad spectrum of bactericidal activity. It acts by dual bactericidal activity by inhibiting dihydrofolate synthetase and dihydrofolic acid reductase.

Titrimetric[4], colorimetric[5] and HPLC methods[6] for sulphadoxine and titrimetric[7] and amperometric methods[8] for sulphalene were earlier reported. The present method utilises the reaction of sulphadoxine and sulphalene with 1, 2-napthaquinone-4-sulphonic acid, sodium salt (NQSA). The chromogens obtained has absorption maximum at 485 nm and obey Beer's law over the concentration range 10 to 50 mcg/ml.

Experimental

Apparatus and Reagents: (i) Pye Unicam SP 1700 Spectrophotometer with 1 cm quartz cells, (ii) 1,2-napthaquinone-4-sulphonic acid, sodium salt (BDH, England) (0.2% w/v): Dissolve 0.2 g of NQSA in 100 ml of water and should be freshly prepared, (iii) Sodium acetate solution (0.5 M): Prepare 0.5 M solution in

* For Corresponcence.

Table 1

Determination of sulphadoxine in dosage forms by the proposed method

Sl. No.	*Sample*	*% of sulpha-doxine*	*Recovery studies*	
			Added (mg)	*% recovery*
1.	Sulphadoxine *	99.5	100	99.9
2	Sulphadoxine	99.8	100	100.2
3	Sulphadoxine-Pyrimeth-amine tablets ** (500 mg + 25 mg)	102.1	100	99.9
4	"	101.8	100	100.2
5	Sulphadoxine-Pyrimeth-amine capsules (500 mg + 25 mg)	101.9	100	99.7
6	"	100.6	100	100.1

* *IP Limits*
Not less than 99.0 % of sulphadoxine on dry basis.
** *USP Limits*
Not less than 90.0% and not more than 110.0% of labelled amount of Sulphadoxine.

water. (iv) Solvents: methanol, isopropyl alcohol, acetic acid of AR grade were used.

Standard Solutions Preparations; Weigh accurately 250 mg. of SD (purity 99.7%) or SP (purity 99.5%) and transfer to a 500 ml. Volumetric flask. Dissolve in 50 ml. of IN Sulphuric acid and dilute to volume with walter.

Preparation of Samples—Drug: Prepare the sample solutions as under standard preparations. *Tablets*; *SD-PM and SP-PM tablets:* Weigh and powder 20 tablets and transfer powder equivalent in 250 mg of SD or SP

Table 2

Determination of sulphalene in dosage forms by the proposed method

Sl. No.	Sample	% of sulpha-lene	Recovery studies	
			Added (mg)	% recovery
1	Sulphalene *	99.6	100	99.5
2	"	99.5	100	99.8
3	Sulphalene -Pyrimetha-mine tablets (500 mg + 25 mg)	100.8	100	99.6
4	"	101.3	100	100.1
5	Sulphalene -Trimetho-prim capsules (200 mg + 250 mg)	102.8	100	100.3
6	"	103.2	100	99.5

* *IP Limits*
Not less than 99% of Sulphalene on dry basis.

to 100 ml beaker, add 50 ml of 1 N sulphuric acid and warm on water bath for 15 minutes, cool and filter into 500 ml calibrated flask and dilute to volume with water. *Capsules: SD-PM and SP-PM capsules-* Pool 20 capsules powder and transfer powder equivalent to 250 mg of SD or SP and prepaer solution as described under tablets.

Assay; Pipette 2 ml each of standard and sample solution in duplicate into separate 25 ml calibrated flasks. Add 5 ml of sodium acetate solution followed by 3 ml of NQSA. After keeping aside at ambient temperature for 20 minutes, add 7.5 ml of glacial acetic acid and dilute to volume with water. Measure the absorbance at 485 nm against a reagent blank.

Results and Discussion

The concentration of NQSA, sodium acetate solution required to yield chromogen with maximum sensitivity were evaluated after conducting several experiments. The chromogens could be extracted into organic solvents (isobutyl methyl ketone, chloroform, toluene, benzene, butyl acetate) to yield yellow colour with absorption maxima in between 425-430 nm. But the sensitivity obtained is less and so, dilution with acetic acid is preferred. Maximum colour development takes 20 minutes after which it is stable for 45 minutes. Under the described experimental conditions, a linear correlation was obtained between absorbance and conceentration in the range 10 - 50 mcg/ml and coefficient of variation was found to be 0.32 (n=6). The molar absorptivity and Sandel's sensitivity were found to be 4.658×10^3 1. mol.$^{-1}$. cm.$^{-1}$ and 0.0666 mcg/cm^2/0.001 for SD and 4.912×10^3 1. mol^{-1}. cm^{-1} and 0.05706 mcg/cm^2/0.001 for SP. The method has been applied for the estimation of dosage forms and results are presented in tables 1 & 2. Precision and repeatability were found in the range 99.7 to 100.3% and 99.5 to 100.2% for SD&; and 99.6 to 100.1% and 99.7 to 100.3% for SP. respectively. Excipients used in formulations like talc, lactose and starch do not interfere in the proposed method. Pyrimethamine or trimethoprim present in combined dosage forms does not interfere under the experimental conditions of the method.

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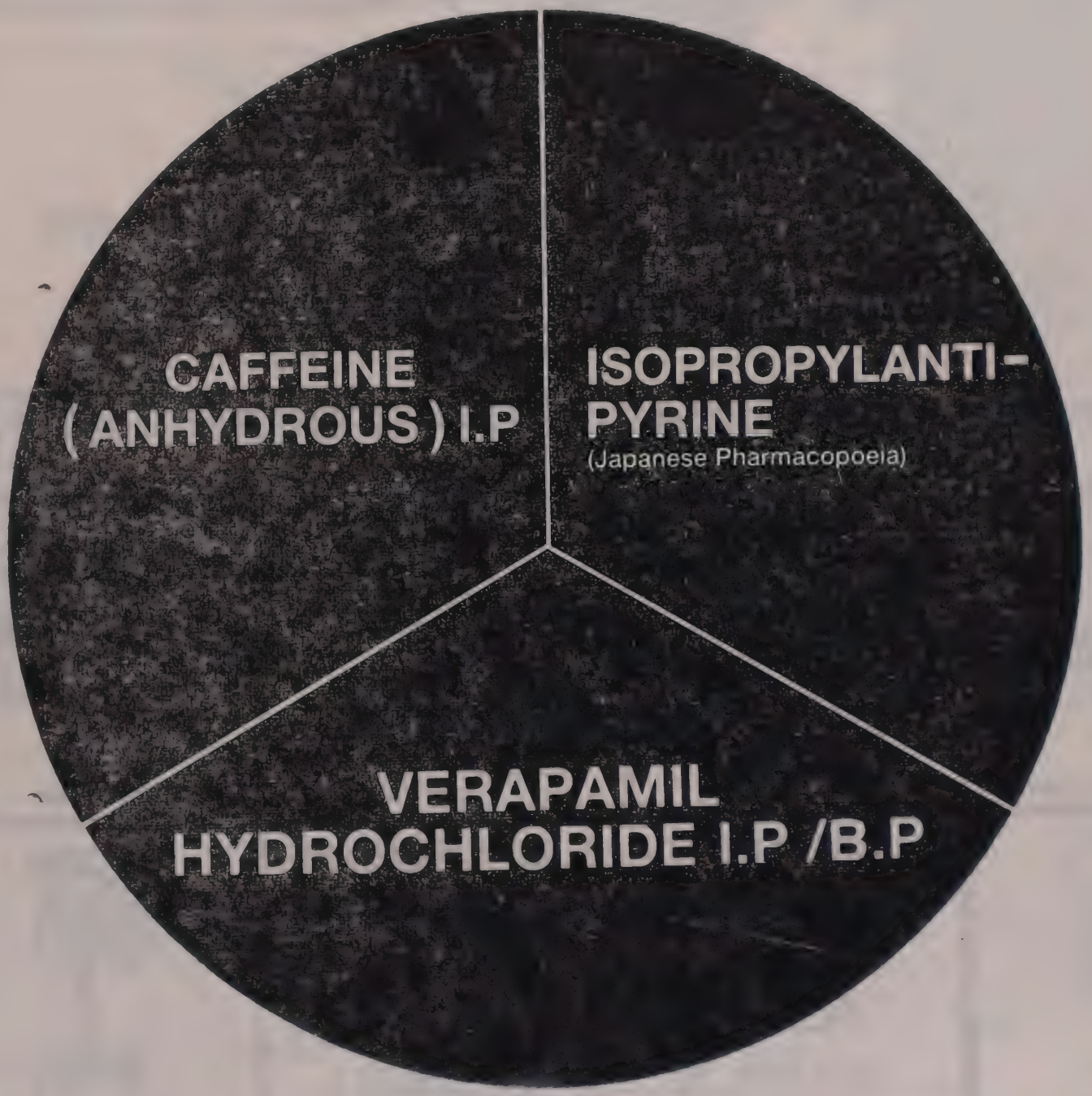

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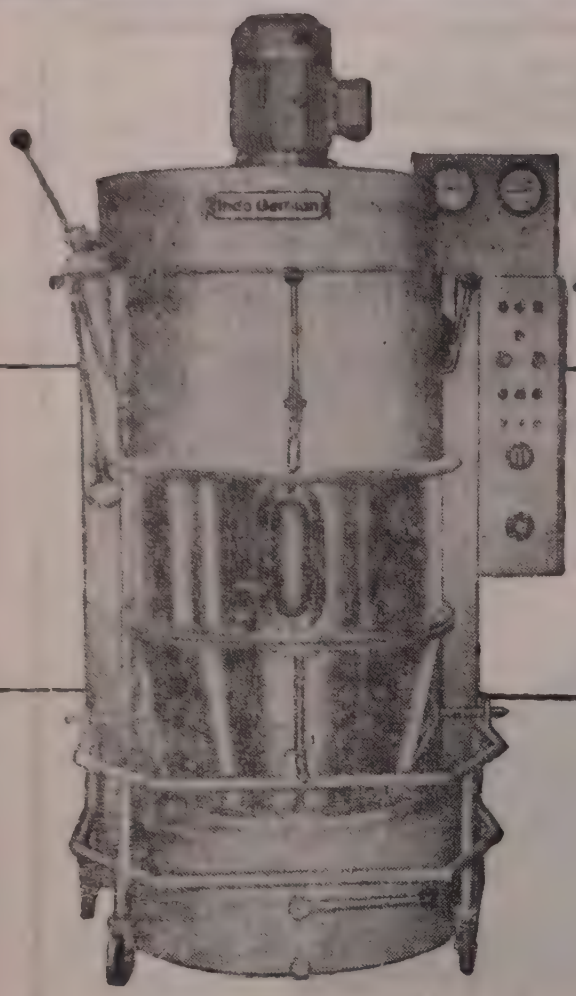

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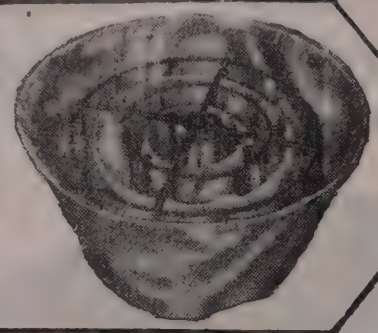

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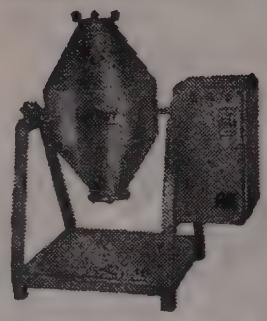
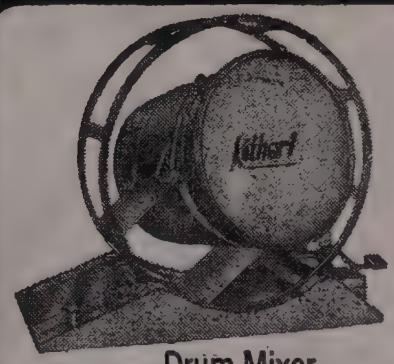


Double Cone Blender



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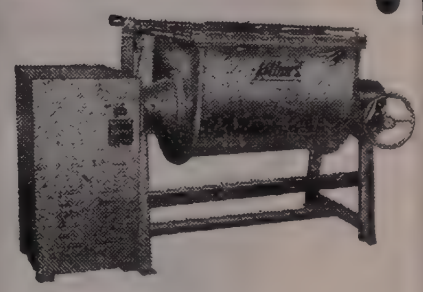

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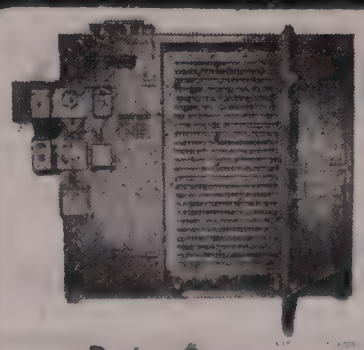

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COLORIMETRIC DETERMINATION OF ISOXSUPRINE HYDROCHLORIDE IN DOSAGE FORMS

Gopal Krishan, Santosh K. Talwar
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Abstract :

A simple and sensitive method for the estimation of Isoxsuprine Hydrochloride in Pharmaceutical preparations is discussed. The color produced in treatment with 4- aminophenazone, and potassium ferricyanide in mild alkaline medium is measured at the maximum of about 502 nm. The recovery studies by way of standard addition to a commercial samples as well as the trial of the proposed method on commercial samples were found satisfactory.

Introduction :

Isoxsuprine Hydrochloride is used in the treatment of cerebral and peripheral vascular disease. It has been found to inhibit contractions of the uterus. Therefore it is used by intravenous injection to arrest premature labour. Isoxsuprine hydrochloride is dispensed in the form of tablets, capsules and injectable preparation. The official method of estimation for the dosage forms is based on spectrophotometric absorption.[1,2] In bulk drugs also uv absorption method is described[2,3] except in B.P. '88 where non- aqueous titrimetry is given. Several colorimetric methods are discussed in the literature.

The present effort is to develop an alternative assay procedure using familiar reaction of the phenolic compounds with 4- aminophenazone and potassium ferricyanide.

Experimental :

All organic and inorganic compounds used in the assay were of analytical reagent grade. Dimineralized water was used wherever required.

Isoxsuprine Hydrochloride used as standard was checked to conform to the specifications in corporated in I.P. 85 before use.

All the commercial samples were procured locally.

4-aminophenazone solution : A 2% w/v solution of 4-aminophenazone in water.

Potassium Ferricyanide solution : 8% w/v solution of Pot. ferricyanide in water.

Sodium Bicarbonate solution : 8.4% w/v solution of sodium bicarbonate in water.

Standard Preparation : An accurately weighed amount of 15 mg of Isoxusuprine hydrochloride was dissolved in 50 ml of water. The final volume was made upto 500 ml with water.

Sample Preparation :

In case of Tablets and Capsules :

The powdered tablets or pooled contents of capsules equivalent to about 15 mg of isoxusuprine hydrochloride was taken in about 100 ml. of water. The solution was heated on a water bath for 5 minutes to dissolve the drug and final volume was made upto 500 ml filtered. Discard initial 10 ml of the filterate.

Table 1

Recovery studies by way of addition of Standard Isoxsuprine HC1 to a commercial sample:

S. No.	Amount added (mg)*	% Recovery**
1.	0.35	99.7
2.	0.45	100.8
3.	0.55	101.2
4.	0.65	99.0
5.	0.75	97.8

*In the final dilution.
* The results are the average of three determinations.

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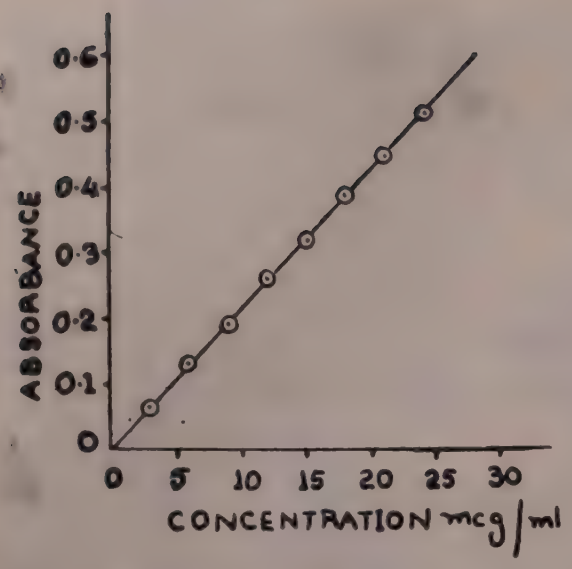

FIG.1-LINEARITY CURVE OF ISOXSUPRINE HCl.

In Case of Injectable Preparation:

Take volume of the pooled injectable vials equivalent to 15 mg in a 500 ml. Volumetric flask. Dilute to volume with water.

Procedure :

Take 50 ml each standard preparation sample preparation and water in separate three 100 ml volumetric flask. Add 1 ml each of 4- aminophenazone solution, potassium ferricyanide soln. and sodium bicarbonate solution in all the flasks and make upto volume with water. After keeping for half an hour the colour produced in case of sample and standard were measured at the maximum of about 502 mn using the third solution in which water has been substituted in place of sample and standard preparations as blank.

Results and Discussion :

The linearity studies conducted with different concentrations of isoxsuprine hydrochloride have shown that the complex formation follows Beer's Law in the range 3 to 24 mcg/ml (Fig. 1) The colour of the complex was found stable for 2 to 3 hours. The reproducibility of the proposed method as well as its utility as a routine analytical method was demonstrated by doing recovery studies by way of standard addition in commercial sample (Table 1) and trial of the method on some commercial samples. (Table 2).

Table 2

Results obtained with the proposed and official procedures on differenct commercial samples for Isoxsuprine HCl.

S. No.	Claim	Obtained		% Claim***	
		I.P. Method	Proposed Method	I.P. Method	Proposed Method
I.	10 mg.	9.62	9.77	96.2	97.7
II.	10 mg.	9.97	10.05	99.7	100.5
III.	20 mg.	20.32	20.51	101.6	102.5
IV	40 mg.	38.55	39.24	96.4	98.1
V.	10 mg/2 ml	10.08	10.20	100.8	102.0

I to III—tablets, IV—Capsules, V-Injectable preparation.

***The results are the average of three determinations.

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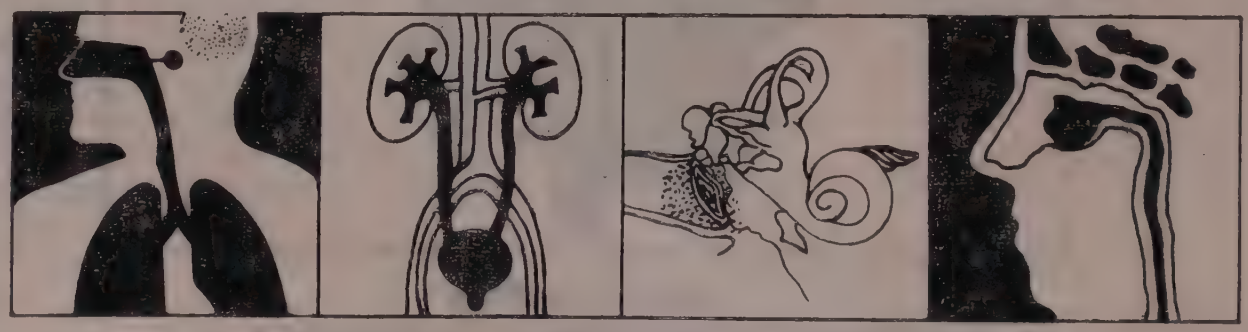

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HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD FOR FRUSEMIDE AND SPIROLACTONE COMBINATION

(Mrs.) S.A. Anapure, Dr. S. Khanna* & V.S. Dighe
Quality Control Labs., Lupin Labs. Ltd., Aurangabad.

Frusemide,[1,2,3] chemically 4-Chloro-N-furfuryl-5-Sulphamoyl-anthranillic acid, is a diuretic and is official drug in I.P., B.P., and U.S.P. Frusemide can be analysed by titrimetric method as presented in the pharmacopoeia. Frusemide tablets are analysed by the UV method. Literature survey reports a titrimetric method for micro estimation of Frusemide,[4] colorimetric method using Phenothiazine[5] and a HPLC method.[6]

Spironolactone,[1,2,3] chemically 7α=Acetylthio-3-Oxo-17 pregne-4-ene 21, 17β Carbolactone acidα lactone, is a diuretic and is official in IP, BP and USP and is analysed by UV method, HPLC method.[3] Spironolactone tablets are analysed by UV method and HPLC method. Literature survey reports spectrophotometric estimation[7,8,9] of Spironolactone.

However, caombination of Frusemide and Spironolactone gives erratic results with UV method and spectrophotometric method. The proposed HPLC/ method is precise for estimation of both the drugs simultaneously from dosage forms.

Experimental :

Waters Associates HPLC equipped with dual piston reciprocating pump (Model 510) and LC Spectrophotometer (Model 481) was used. The analysis was performed using Waters NOVAPAK C-18 column. The eluent was monitored at 254 nm. Detector sensitivity was set at 0.5 AUFS and the chromatograms were recorded on a computing integrator with a chart speed of 0.5cm/min. The flow rate was 1 ml/min.

Reagents :

(i) Acetonitrile (SD's HPLC grade)

(ii) Diammonium Hydrogen Orthophosphate (SD's purified grade)

(iii) Phosphoric acid (Analar grade, Qualigens)

Mobile phases :

A mixture of 55 parts of Acetonitrile and 45 parts of 0.02 M diammonium hydrogen orthophosphate, pH 4.0 adjusted with orthophosphoric acid was used as the mobile phase after filtering it through a 0.2 micron porosity membrance filter.

Standard Preparation:

Standard Frusemide Stock :

50 mg of Frusemide reference standard was accurately weighed in a 50ml volumetric flask containing 30ml of acetonitrile. The drug was dissolved and the volume was made up to the mark with acetonitrile.

Standard Spironolactone Stock :

125 mg. of Spironolactone reference standard was accurately weighed in a 50ml volumetric flask containing 30ml of acetonitrile. The drug was dissolved and the volume was made up to the mark with acetonitrile.

Working Standard :

5ml each of Frusemide and Spironolactone stock solution were transferred in a 25ml volumetric flask and the volume was made upto the mark with mobile phase. Further, 5ml of this solution was diluted to 50ml in a volumetric flask with the mobile phase.

Test Preparation :

Twenty tablets were weighed and crushed them to a fine powder. 80mg of the powder was accurately weighed in a 50ml volumetic flask containing 30ml of acetonitrile. The powder was dispersed and the volume was made upto the mark with acetonitrile. The preparation was stirred on a magnetic stirrer for 15 mins. The preparation was filtered and initial filterate (5-10 ml) was discareded before use. 5ml. of this filterate was diluted to 50ml in a volumetric flask with mobile phase.

Assay Procedure :

Working standard and test preparations were injected

*For correspondence

Table I

Product	Label Claim		% Recovery by Proposed Method	
			Frusemide	Spironolactone
1. Frusemide Drug	—		99.95	—
2. Spironolactone Drug	—		—	100.9
3. Frusemide and Spironolactone Tablets	Frusemide 20mg/tab	Tab 'A'	100.12%	97.89%
	Spirono-lactone 50mg/tab	Tab 'B'	99.29%	98.96%

Tablet 'A' and Tablet 'B' are two different batches of the same manufacturer. The values reported are the average of triplicate analysis.

separately through a Rheodyne injector holding a 20 microlitre loop and the chromatograms were recorded.

The percentage of drug per tablet was calculated using area under the curve. The retention time of Frusemide was found to be at 1.58 mins. and that of Spironolactone was 3.24 mins.

Linearity :

The linearity of Frusemide and Spironolactone was checked separately. The drug concentration was plotted against area under the curve. For Frusemide the curve was found to be linear in the range of 0 to 48 mcg/ml and that of Spironolactons in the range of 0 to 120 mcg/ml.

Recovery Studies :

Known amount of Frusemide and Spironolactone were added to the placebo and were estimated as described in the assay procedure. The results are given in Table II. The precision of the method was found to be in the range of 97.36% to 100.71%.

Results and Discussion :

The proposed mobile phase and the flow rate was found to be ideal for the separation of Frusemide and Spironolactone. The retention time of Frusemide was 1.58 mins. and that of Spironolactone was 3.24 mins.

The reslts obtained for Frusemide drug, Spironolactone drug, and their combination tablets are shown in Table I.

Table II

Recovery Studies

	Added Amount (mg/50ml)		Estimated Amount (mg/50ml)		% Recovery	
	Frusemide	Spironolactone	Frusemide	Spironolactone	Frusemide	Spironolactone
1.	0.4	1.0	0.3963	0.9857	99.07	98.57
2.	0.8	2.0	0.7930	1.9482	99.12	97.36
3.	1.2	3.0	1.177	2.9574	98.12	98.58
4.	1.6	4.0	1.571	3.9252	98.19	98.13
5.	2.0	5.0	1.969	4.962	98.43	99.24
6.	2.4	6.0	2.417	5.8986	100.71	98.31

Standard Deviation : Frusemide 0.9672 ; Spironolactone 0.634.
Relative Standard Deviation : Frusemide 0.9775 ; Spironolactone 0.645.

Acknowledgement :

The authors are thankful to Mr Yateen Shah for his assistance.

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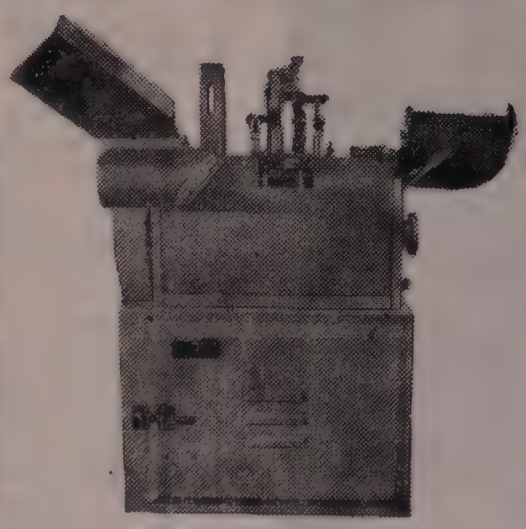

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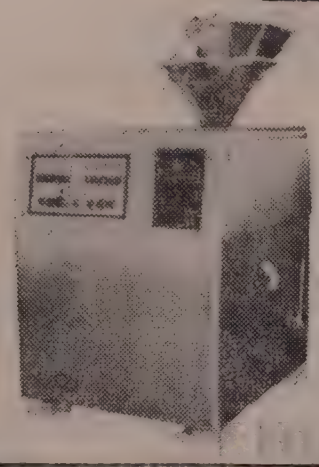

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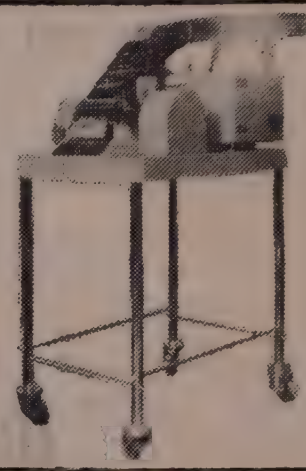

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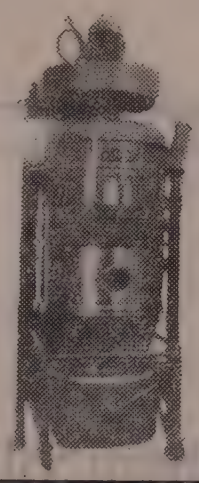

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A

Acila Pharmaceuticals Pvt. Ltd.	196
Adept Engineers	86
Adrian Engg. Works	158
Aimil Pharmaceuticals (I) Pvt. Ltd.	Cover II
Alarsin Marketing Pvt. Ltd.	97, 120
Albert David Ltd.	127
Alliance Engg. Co.	172
Altraclean Apparles	43
Amar Engg. Works	46
Amba Engineers	174
Ambica Inds. Corporation	160
Apt Equipment & Control Systems	122
Arvind Engg. Works	182
Associated Capsules Pvt. Ltd.	Cover I
Associated Drug Co. (P) Ltd.	187

B

Batliboi & Co. Ltd.	36, 159
B. H. Chemical Works (P) Ltd.	72
Bhuvaneswari Corporation	181, 191
Biogenics (India) Ltd.	197
British Medical Stores	42

C

Cadmach Machinery Co. Pvt. Ltd.	1, 198
Campbell Electronics	166
Carminol Labs. (P) Ltd.	21
Citurgia Biochemicals Ltd.	104
Clit Marketing & Services Pvt. Ltd.	143
Collapsible Tube Corporation	52,119

D

Design Centre	142
Dinesh Chemicals Pvt. Ltd.	8
Dowel (India) Pvt. Ltd.	30

E

Electrolab	130
Elmach Packages (I) Pvt. Ltd.	12
Entod Pharmaceuticals	38
Esschem (Pvt) Ltd.	177
Essjee Pharmaceuticals	85
Everest Pharmaceutics (P.) Ltd.	133
Excel Techno Engrs (P.) Ltd.	164

F

Fabrica Steel Corpn.	144
Farmson Pharmaceutical Gujarat Pvt. Ltd.	16
Franco-Indian Pharmaceuticals Ltd.	59
Fusion Polymers Pvt. Ltd.	75

H

Harsiddh Industries	170
H. B. Mechanical & Engg. Works	37
HiMedia Labs. Pvt. Ltd.	15
Hunjan Machine Tools	80

I

Indian Equipment Corpn.	9,134,164
Indian National Drug Co. Pvt. Ltd.	144
Integrated Process Automation Pvt. Ltd.	157

J

Jacsons Sales India	142
Jaydev Engg. Corpn.	160
J.B. Chemicals & Pharmaceuticals	195
J.T. Jagtiani	35

K

Kalika Glass Industries	132
Khambhaita Bros.	184
Komal Industries	165
Kothari Automatics Inds.	188
Kulbindra Engg. Works	61
Kumar Process Consultants & Chemicals Pvt. Ltd.	22
	199

L

Laxmi Engrs. Equipment 171

M

Magumps 124
Mech Combine 109
Medimpex 5
Meena Engg. Works 147
Mevish Pharmaceutical & Equipment Works 176
Mixofill India 23
Monga Packaging Pvt. Ltd. 184

N

Neo Machine Mfg. Co. Pvt. Ltd. 24
Nimach Engg. Co. 158
Nimco Engg. Corpn. 76

O

Oriental Machinery (1919) Pvt. Ltd. 146

P

Paam Pharmaceuticals (Delhi) Ltd. 7
Pam Pharmaceutical & Allied Machinery Co. Pvt. Ltd. Cover IV
Pharmaceutical Equipment 196
Pharmaceutical & Surgical Equipments 123
Pharmadeals 14
Pharmagents 28
Pharmalab (Group) Marketing Agency 95, 96,173
Pharma Mach 45
Pharmech Engg. Corpn. 53
Pharnova Organics 178
P.L. Tandon & Co. 128
Port Shipping Co. Ltd. 148
Promivac Engineers 128
Process Chemicals Co. 50

R

Rajdhani Imports & Exports 98
Ranbaxy Labs. Ltd. 183
Rank & Co. 73
Rathi Papains Pvt. Ltd. 141
Rays Labs. Pvt. Ltd. 54
Reddy Engg. Works 68
Roche Products Ltd. 51
Rupa Industries 74

S

Sarabhai Chemicals 192
Sarabhai M Chemicals 179
Saral Engg. Co. 66
Scientific Apparatus Co. 110
Sehgal Industrial Works 67
Shreema Chemicals (P) Ltd. 65
Sigma Laboratories 62
S. S. Engg. Works 60
S. S. Industries 106
Stadmed Pvt. Ltd. 175
Strip India 44
Sunny Inds. Pvt. Ltd. 135

U

United Engg. Co. Cover III
United Pharma International Ltd. 2
Usan Pharmaceuticals Pvt. Ltd. 6

V

V. Tribhovandas Pvt. Ltd. 121

W

Wang Pharmacenticals & Chemicals 197
Warkem 10

Y

Y. Vakil & Co. 131

Z

Zeolite (I) Pvt. Ltd. 29

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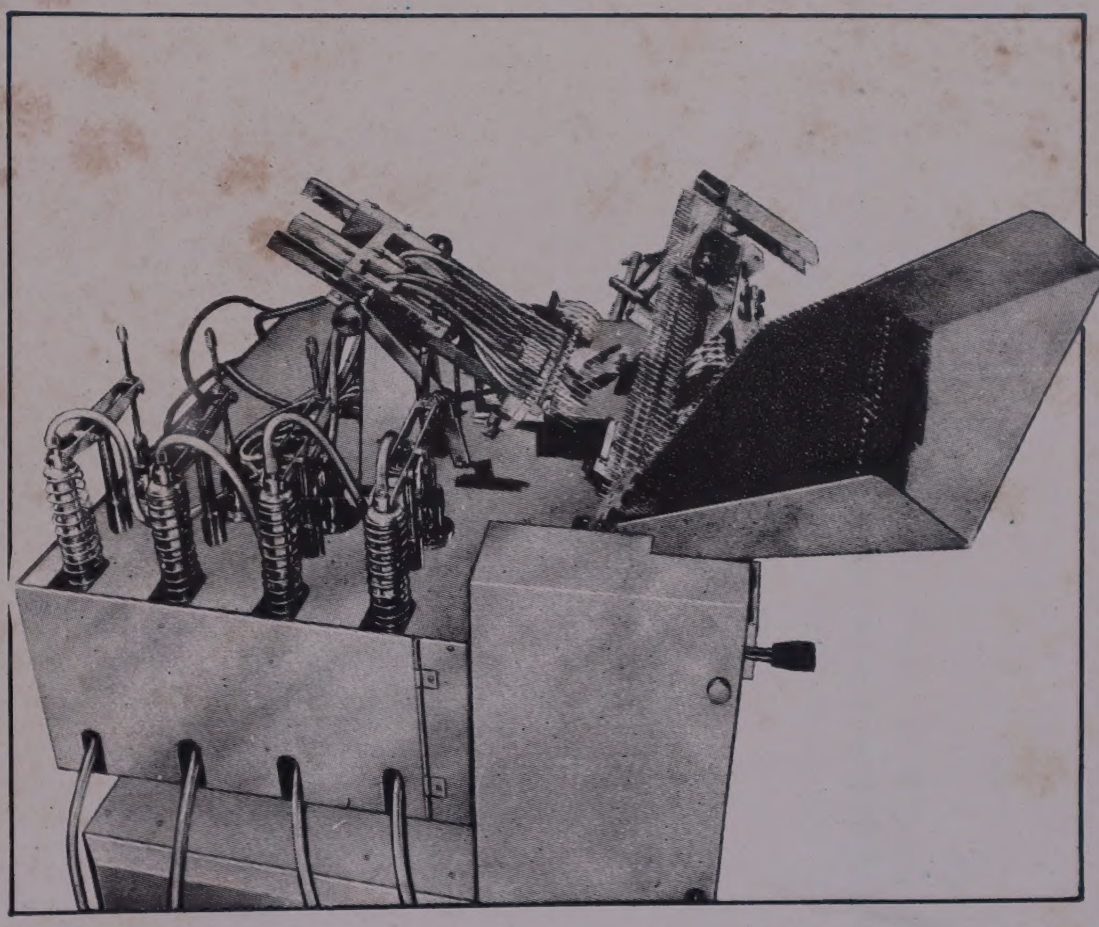

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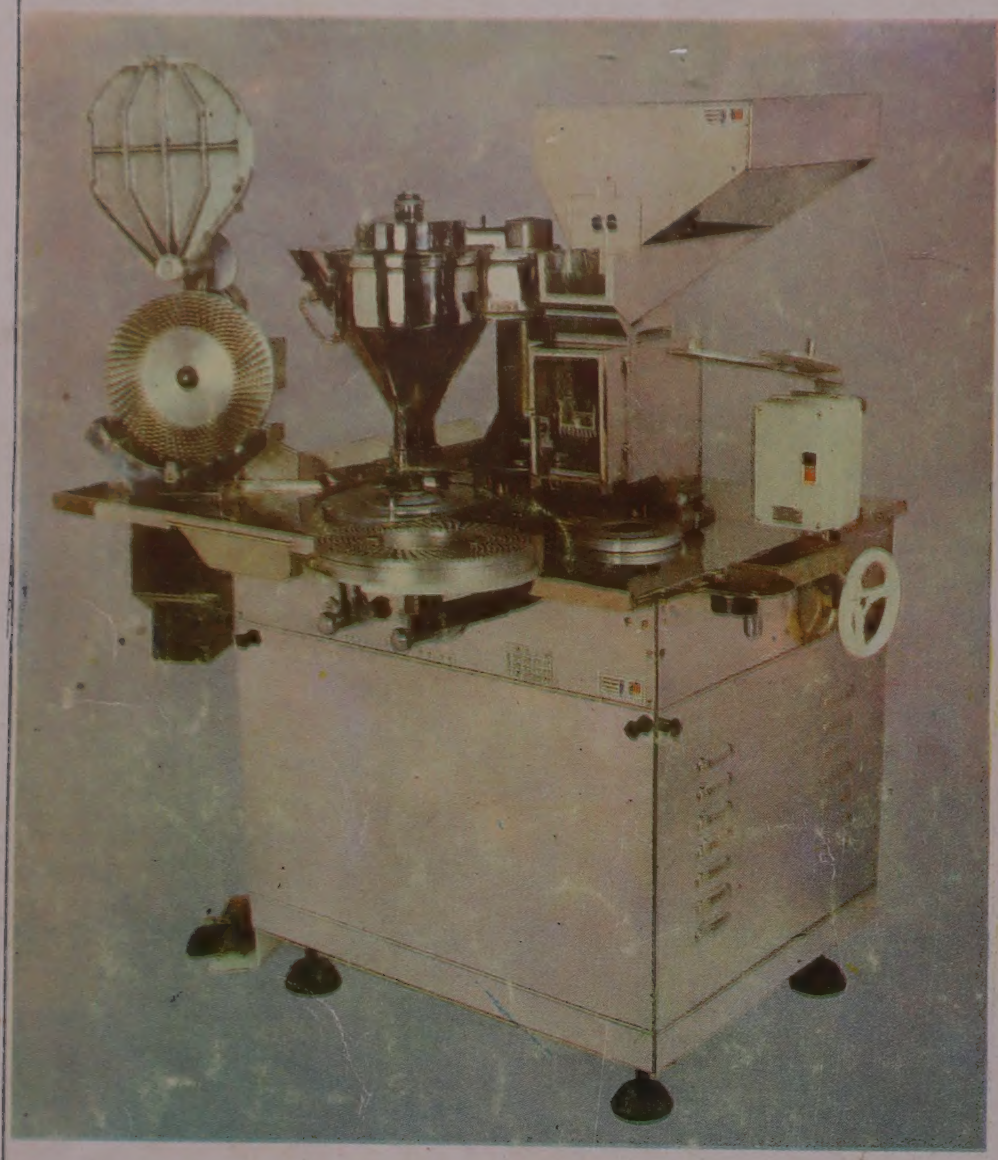

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